



Congress Brochure

BeSTRO Autumn Meeting 2026

“Combined therapy”

WHEN

Friday 9 & Saturday 10 October 2026

WHERE

Palais des Congrès de Mons

Conference center of Van der Valk Mons
Avenue Mélina Mercouri 9, 7000 Mons

WELCOME

Welcome to the BeSTRO Autumn Meeting 2026

Dear colleagues,

On behalf of the **BeSTRO/BARO board** and the scientific committee, it is my great pleasure to welcome you to our Annual Autumn Meeting 2026, taking place on **9–10 October 2026** at the **Palais des Congrès de Mons**.

This year's meeting is centred around the theme **“Combined Therapy”**, a topic that reflects the increasingly multidisciplinary nature of modern cancer care. As treatment strategies continue to evolve, collaboration between radiotherapy and other therapeutic modalities plays an essential role in improving patient outcomes. We are delighted to bring together national and international experts who will share the latest scientific developments, clinical experience, and future perspectives in this rapidly advancing field.

Over the course of the meeting, you will have the opportunity to attend a diverse scientific programme. We will start with broad overviews on the advantages and risks of combination therapy in both the clinical and pre-clinical setting, followed by disease-specific sessions focusing on head and neck, lung, gastrointestinal and breast cancer. In addition, dedicated lectures will provide updates on topics of direct relevance to our daily practice, including the nomenclature. As always, we are also pleased to provide a platform for our junior colleagues to present their work and contribute to the scientific discussion.

I would like to express my sincere gratitude to the scientific committee for their dedication in putting together this excellent programme, as well as to all speakers for sharing their expertise. I would also like to thank our partners for their continued support, which makes this meeting possible. We encourage you to visit the exhibition area during the breaks and engage with our sponsors.

Finally, I would like to thank all of you for being part of our BeSTRO/BARO community. Your enthusiasm, commitment, and active participation are what make this meeting such a valuable opportunity to learn from one another and strengthen our professional network.

I wish you an inspiring meeting and a pleasant stay in Mons.

Paul Meijnders

President, BeSTRO/BARO

Practical information

DATES

Friday 9 October 2026

Saturday 10 October 2026

Friday from 13:30 · Saturday from 08:30

VENUE

Conference center

Palais des Congrès de Mons

Avenue Mélina Mercouri 9

7000 Mons

www.palaisdescongresmons.be/nl

Next to the Van der Valk Hotel Mons



Left: Van der Valk Hotel · right: the conference center Palais des Congrès de Mons (Avenue Mélina Mercouri 9, 7000 Mons)

VISIT THE EXHIBITION

Our partners welcome you in the **Atrium** (ground floor) during registration and the coffee breaks.

Friday 9 October

13:30 · Registration & welcome coffee

15:20 · Coffee break

Saturday 10 October

08:30 · Registration & welcome coffee

10:05 · Coffee break

Our partners

GOLD PARTNERS



SILVER PARTNERS



BRONZE PARTNERS



YOUR BEAMS.

We are a trusted partner in what comes next.



PACIFIC¹

Locally advanced unresectable NSCLC
with PDL-1 expression > 1%

ADRIATIC¹

Limited stage SCLC

LAURA²

Locally advanced unresectable NSCLC
with activating EGFR-mutation
[EXON-19-DEL + EXON-21 (L858R)]



CISPLATIN
OR CARBOPLATIN

(For ADRIATIC indication: + ETOPOSIDE)



RADIOTHERAPY
(concomitant or sequential)

Min
2
cycles

UP TO
12 MONTHS[#]

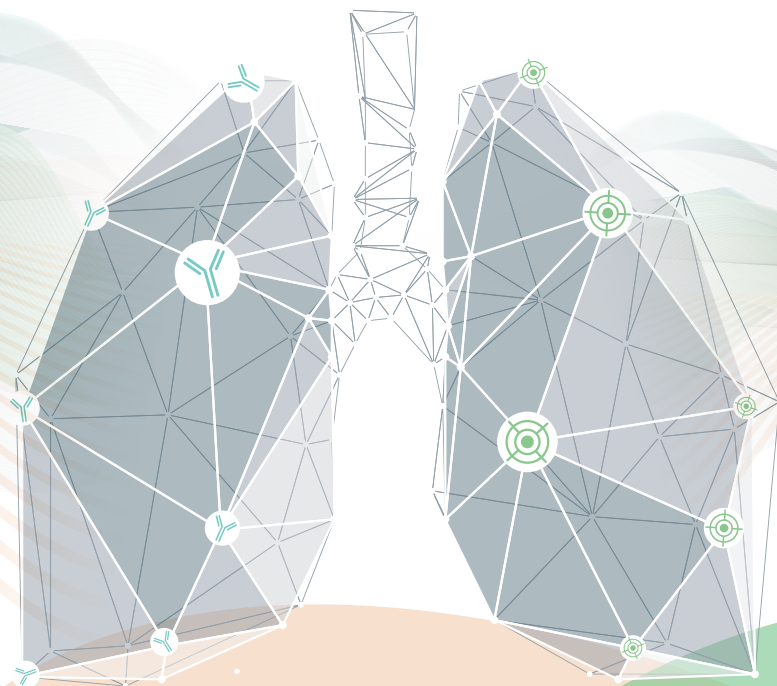
Up to
4
cycles

UP TO
24 MONTHS[#]

Min
2
cycles

UNTIL DISEASE
PROGRESSION

* No disease progression during or following CT ; # Until disease progression or unacceptable toxicity



References: 1. SmPC IMFINZI[®], latest version; 2. SmPC TAGRISSO[®], latest version

Abbreviations: CT = Chemotherapy; RT = Radiotherapy; NSCLC = Non-Small Cell Lung Cancer; SCLC = Small Cell Lung Cancer; EGFR = Epidermal Growth Factor Receptor; PDL-1 = Programmed cell Death-Ligand 1

NS ID XL-4069-Revision date 02/2026-VA Local code: 252

ESSENTIAL INFORMATION. 1. NAME OF THE MEDICINAL PRODUCT. TAGRISSO 40 mg film-coated tablets. TAGRISSO 80 mg film-coated tablets. **2. QUALITATIVE AND QUANTITATIVE COMPOSITION.**

TAGRISSO 40 mg tablets. Each tablet contains 40 mg osimertinib (as mesylate). TAGRISSO 80 mg tablets. Each tablet contains 80 mg osimertinib (as mesylate). **Excipient with known effect.** *TAGRISSO 40 mg tablets.* Each tablet contains 0.3 mg sodium. *TAGRISSO 80 mg tablets.* Each tablet contains 0.6 mg sodium. For the full list of excipients, see section 'List of excipients' of the SmPC. **3. PHARMACEUTICAL FORM.** Film-coated tablet (tablet). TAGRISSO 40 mg tablets. Beige, 9 mm, round, biconvex tablet, debossed with "AZ" and "40" on one side and plain on the reverse. TAGRISSO 80 mg tablets. Beige, 7.25 x 14.5 mm, oval, biconvex tablet, debossed with "AZ" and "80" on one side and plain on the reverse. **4. CLINICAL PARTICULARS. 4.1 Therapeutic indications.** TAGRISSO as monotherapy is indicated for:

• the adjuvant treatment after complete tumour resection in adult patients with stage IB-IIIA non-small cell lung cancer (NSCLC) whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations (see section 'Pharmacodynamic properties' of the SmPC); • the treatment of adult patients with locally advanced, unresectable NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following platinum based chemoradiation therapy. • the first-line treatment of adult patients with locally advanced or metastatic NSCLC with activating EGFR mutations. • the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC. TAGRISSO is indicated in combination with: • pemetrexed and platinum-based chemotherapy for the first-line treatment of adult patients with advanced NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations. **4.2 Posology and method of administration.** Treatment with TAGRISSO should be initiated by a physician experienced in the use of anticancer therapies. When considering the use of TAGRISSO, EGFR mutation status (in tumour specimens for adjuvant treatment or for treatment of locally advanced, unresectable tumours and tumour or plasma specimens for locally advanced or metastatic setting) should be determined using a validated test method (see section 'Special warnings and precautions for use' of the SmPC). **Posology. Monotherapy.** The recommended dose is 80 mg osimertinib once a day. **Combination therapy.** The recommended dose of TAGRISSO is 80 mg osimertinib once a day when taken with pemetrexed and platinum-based chemotherapy. Refer to the Summary of Product Characteristics for pemetrexed and cisplatin or carboplatin for the respective dosing information. Patients in the adjuvant setting should receive treatment until disease recurrence or unacceptable toxicity. Treatment duration for more than 3 years was not studied. Patients with locally advanced or metastatic lung cancer should receive TAGRISSO treatment until disease progression or unacceptable toxicity. If a dose of TAGRISSO is missed, the dose should be made up unless the next dose is due within 12 hours. TAGRISSO can be taken with or without food at the same time each day. **Dose adjustments.** Dosing interruption and/or dose reduction may be required based on individual safety and tolerability. If dose reduction is necessary, then the dose should be reduced to 40 mg taken once daily. Dose reduction guidelines for adverse reactions to pemetrexed are provided in Table 1. **Table 1.**

Recommended dose modifications for TAGRISSO (Target organ: Adverse reaction: Dose modification). **Pulmonary:** Adverse reaction: ILD/Pneumonitis; Dose modification: Permanently discontinue TAGRISSO. Adverse reaction: Grade 1 Radiation Pneumonitis; Dose modification: Consider withholding or continue TAGRISSO, as clinically indicated. Adverse reaction: Grade 2 Radiation Pneumonitis; Dose modification: Withhold TAGRISSO until symptoms resolve. TAGRISSO may be restarted. Permanently discontinue if symptoms do not resolve after 4 weeks or Grade 2 Radiation Pneumonitis recurs. Adverse reaction: Grade 3 or 4 Radiation Pneumonitis; Dose modification: Permanently discontinue TAGRISSO. **Cardiac:** Adverse reaction: QTc interval greater than 500 msec, on at least 2 separate ECGs. Dose modification: Withhold TAGRISSO until QTc interval is less than 481 msec (or recovery to baseline if baseline QTc is greater than or equal to 481 msec), then restart at a reduced dose (40 mg). Adverse reaction: QTc interval prolongation with signs/symptoms of serious arrhythmia; Dose modification: Permanently discontinue TAGRISSO. **Cutaneous:** Adverse reaction: Stevens-Johnson Syndrome and Toxic epidermal necrolysis; Dose modification: Permanently discontinue TAGRISSO. **Blood and lymphatic system:** Adverse reaction: Aplastic anaemia; Dose modification: Permanently discontinue TAGRISSO. **Other:** Adverse reaction: Grade 3 or higher adverse reaction; Dose modification: Withhold TAGRISSO for up to 3 weeks. Adverse reaction: If Grade 3 or higher adverse reaction improves for Grade 2-2 after withholding of TAGRISSO for up to 3 weeks; Dose modification: TAGRISSO may be restarted at the same dose (80 mg) or a lower dose (40 mg). Adverse reaction: Grade 3 or higher adverse reaction that does not improve for Grade 2-2 after withholding for up to 3 weeks; Dose modification: Permanently discontinue TAGRISSO. **Note:** The intensity of clinical adverse events graded by the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. ⁴ Refer to section 'Special warnings and precautions for use' of the SmPC. ¹ ILD/Pneumonitis including ILD/Pneumonitis following definitive platinum-based chemoradiation therapy. ECGs: Electrocardiograms; QTc: QT interval corrected for heart rate. **Combination therapy.** When TAGRISSO is used in combination, any of the treatment components should be dose modified, as appropriate. For TAGRISSO dose modification instructions, see Table 1. The pemetrexed, cisplatin or carboplatin dose should be modified in accordance with the instructions in their respective Summary of Product Characteristics. Cisplatin and/or carboplatin should be used for up to 4 cycles. **Special populations.** No dose adjustment is required due to patient age, body weight, gender, ethnicity and smoking status (see section 'Pharmacokinetic properties' of the SmPC). **Hepatic impairment.** Based on clinical studies, no dose adjustments are necessary in patients with mild hepatic impairment (Child Pugh A) or moderate hepatic impairment (Child Pugh B). Similarly, based on population pharmacokinetic analysis, no dose adjustment is recommended in patients with mild hepatic impairment (total bilirubin upper limit of normal (ULN) and aspartate aminotransferase (AST) >ULN or total bilirubin >1.0 to 1.5 times ULN and any AST) or moderate hepatic impairment (total bilirubin population pharmacokinetic analysis, no dose adjustment is recommended in patients with mild hepatic impairment. Until additional data become available, use in patients with severe hepatic impairment is not recommended (see section 'Pharmacokinetic properties' of the SmPC). **Renal impairment.** Based on clinical studies and population PK analysis, no dose adjustments are necessary in patients with mild, moderate, or severe renal impairment. The safety and efficacy of this medicinal product has not been established in patients with end-stage renal disease (creatinine clearance (CLcr) less than 15 mL/min, calculated by the Cockcroft and Gault equation), or on dialysis. Caution should be exercised when treating patients with severe and end-stage renal impairment (see section 'Pharmacokinetic properties' of the SmPC). **Pediatric population.** The safety and efficacy of TAGRISSO in children or adolescents aged less than 18 years have not been established. No data are available. **Method of administration.** This medicinal product is for oral use. The tablet should be swallowed whole with water and it should not be crushed, split or chewed. If the patient is unable to swallow the tablet, the tablet may first be dispersed in 50 mL of non carbonated water. It should be dropped in the water, without crushing, stirred until dispersed and immediately swallowed. An additional half a glass of water should be added to ensure that no residue remains and then immediately swallowed. No other liquids should be added. If administration via nasogastric tube is required, the same process as above should be followed but using volumes of 15 mL for the initial dispersion and 15 mL for the residue rinses. The resulting 30 mL of liquid should be administered as per the nasogastric tube manufacturer's instructions with appropriate water flushes. The dispersion and residues should be administered within 30 minutes of the addition of the tablets to water. **4.3 Contraindications.** Hypersensitivity to the active substance or to any of the excipients listed in section 'List of excipients' of the SmPC. **4.4 Warnings and precautions.** **4.4.1 Important safety information.** **4.4.1.1 Important safety information.** **4.4.1.2 Important safety information.** **4.4.1.3 Important safety information.** **4.4.1.4 Important safety information.** **4.4.1.5 Important safety information.** **4.4.1.6 Important safety information.** **4.4.1.7 Important safety information.** **4.4.1.8 Important safety information.** **4.4.1.9 Important safety information.** **4.4.1.10 Important safety information.** **4.4.1.11 Important safety information.** **4.4.1.12 Important safety information.** **4.4.1.13 Important safety information.** **4.4.1.14 Important safety information.** **4.4.1.15 Important safety information.** **4.4.1.16 Important safety 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Ex-factory price excl. VAT		Reimbursed
500 mg/10 ml	€2,487.69	100%
120 mg/2.4 ml	€597.05	

PROGRAMME

Friday 9 October 2026

13:30 Registration, welcome coffee & exhibition

14:30 Welcome by the president

Junior abstracts

14:35 Assessing interinstitutional variability in delineation and treatment planning for pancreatic Stereotactic Body Radiotherapy: a pretrial benchmark analysis of the TORPEDO Study
Daan Stas (Iridium Network)

14:45 Long-term recurrence patterns in rectal cancer after neoadjuvant therapy: 25 years of real-world data
Pieter Maerten (UZ Leuven)

Honorary Member Lectures

Moderator: Caroline Weltens (UZ Leuven)

14:55 General introduction on the advantages and risks of combination therapy in the clinical setting
Dirk De Ruyscher (Maastru)

15:20 Coffee break & exhibition

Moderators: Katrien Vandecasteele (UZ Gent) & Christelle Bouchart (Institut J. Bordet)

16:05 General introduction on the advantages and risks of combination therapy in the pre-clinical setting
Eric Deutsch (Gustave Roussy Institute)

Update Lectures

16:45 In Memoriam: Dr. François-Xavier Otte · Alex De Caluwé
The College of Radiotherapy · Reinhilde Weytjens
National Cancer Plan V2 · Dirk Van Gestel (BeBO)
B-ROG · Jean-François Daisne
General Assembly BeSTRO-BARO · Paul Meijnders, Benedikt Engels

18:25 Closure

18:30 Reception & dinner, followed by a social event

Visit our partners in the exhibition area (Atrium) during these moments.

This is real. This is efficacy¹ in action.



67 MILLION
treatment months⁴

<10 NG/DL
sustained testosterone
suppression¹

R RELIABILITY²

E EFFICACY¹

A ADAPTABILITY³

L LEGACY



References: ¹ Klotz L, Tat T. BJU Compass. 2024;5(3):392–402; ² Heyns CF, et al. BJU Int. 2003;92(3):226–231; ³ Decapeptyl® SR 3,75 mg Summary of Product Characteristics, Decapeptyl® SR 11,25 mg Summary of Product Characteristics, Decapeptyl® SR 22,5 mg Summary of Product Characteristics; ⁴ Ipsen Data on File. Pack shot is only there for illustrative purposes and do not necessarily represent the actual available local package.

NAME OF THE MEDICINAL PRODUCT Decapeptyl Sustained Release 22.5 mg powder and solvent for prolonged-release suspension for injection. **QUALITATIVE AND QUANTITATIVE COMPOSITION** Each vial contains triptorelin pamoate equivalent to 22.5 mg triptorelin. After reconstitution in 2 ml solvent, 1 ml of reconstituted suspension contains 11.25 mg of triptorelin. For a full list of excipients see section 6.1. **PHARMACEUTICAL FORM** Powder and solvent for prolonged-release suspension for injection. **Therapeutic indications** Decapeptyl Sustained Release 22.5 mg is indicated for the treatment of locally advanced or metastatic, hormone-dependent prostate cancer. Decapeptyl Sustained Release 22.5 mg is indicated in the treatment of high-risk localised or locally advanced hormone-dependent prostate cancer in combination with radiotherapy. See section 5.1. Decapeptyl Sustained Release 22.5 mg is indicated for the treatment of central precocious puberty (CPP) in children of 2 years and older with an onset of CPP before 8 years in girls and 10 years in boys. **Posology and method of administration** Posology The recommended dose of Decapeptyl Sustained Release 22.5 mg is 22.5 mg triptorelin (1 vial) administered every six months (twenty four weeks) as a single intramuscular injection. In high-risk localised or locally advanced hormone-dependent prostate cancer as concomitant to and following radiation therapy clinical data have shown that radiotherapy followed by long-term androgen deprivation therapy is preferable to radiotherapy followed by short-term androgen deprivation therapy. See section 5.1. The treatment duration of androgen deprivation therapy recommended by medical guidelines for patients with high-risk localised or locally advanced prostate cancer receiving radiotherapy is 2-3 years. In patients with metastatic castration resistant prostate cancer who are not surgically castrated receiving a GnRH agonist, such as triptorelin, and eligible for treatment with abiraterone acetate, an inhibitor of androgen biosynthesis, or enzalutamide, an inhibitor of androgen receptor function, treatment with the GnRH agonist should be continued. *Patients with renal or hepatic impairment* No dosage adjustment is necessary for patients with renal or hepatic impairment. *Paediatric population* Precocious puberty (before 8 years in girls and 10 years in boys) The treatment of children with Decapeptyl Sustained Release 22.5 mg should be under the overall supervision of a paediatric endocrinologist or of a paediatrician or an endocrinologist with expertise in the treatment of central precocious puberty. Treatment should be stopped around the physiological age of puberty in boys and girls and should not be continued in girls with a bone maturation of more than 12-13 years. There are limited data available in boys relating to the optimum time to stop treatment based on bone age, however it is advised that treatment is stopped in boys with a bone maturation age of 13-14 years. **Method of administration** As with other medicinal products administered by injection, the injection site should be varied periodically. Once reconstituted, the suspension of Decapeptyl Sustained Release 22.5 mg should be intramuscularly injected relatively rapidly and uninterrupted manner in order to avoid any potential blockage of the needle. **Precautions to be taken before handling or administering the product** Decapeptyl Sustained Release 22.5 mg is only intended for intramuscular use. Since Decapeptyl Sustained Release 22.5 mg is a suspension of microgranules, inadvertent intravascular injection must be strictly avoided. Decapeptyl Sustained Release 22.5 mg must be administered under the supervision of a physician. For instructions on reconstitution of the medicinal product before administration, see section 6.6. **Contraindications** Hypersensitivity to GnRH, its analogues or to any of the excipients of the medicinal product listed in section 6.1 (see also section 4.8). Triptorelin is contraindicated during pregnancy and lactation (see section 4.6). **Undesirable effects** General **tolerance** in men Since patients suffering from locally advanced or metastatic, hormone-dependent prostate cancer are generally old and have other diseases frequently encountered in this aged population, more than 90 % of the patients included in clinical trials reported adverse events, and often the causality is difficult to assess. As seen with other GnRH agonist therapies or after surgical castration, the most commonly observed adverse events related to triptorelin treatment were due to its expected pharmacological effects. These effects included hot flushes and decreased libido. With the exception of immuno-allergic (rare) and injection site (< 5%) reactions, all adverse events are known to be related to testosterone changes. The following adverse reactions considered as at least possibly related to triptorelin treatment were reported. Most of these events are known to be related to biochemical or surgical castration. The frequency of the adverse reactions is classified as follows: very common (≥1/100, <1/10); common (≥1/1000, <1/100); uncommon (≥1/10000, <1/1000); rare (≥1/10000, <1/1000); not known (cannot be estimated from the available data). **Infections and infestations** Nasopharyngitis **Rare Blood and lymphatic system disorders** Thrombocytosis *Uncommon* Anaemia *Additional post-marketing data* Frequency not known **Immune system disorders** Hypersensitivity *Common* Anaphylactic reaction *Rare* Anaphylactic shock *Additional post-marketing data* Frequency not known **Metabolism and nutrition disorders** Anorexia Diabetes mellitus Gout Hyperlipidaemia Increased appetite *Uncommon* **Psychiatric disorders** Libido decreased *Very Common* Depression* Loss of libido Mood changes* *Common* Insomnia Irritability *Uncommon* Confusional state Decreased activity Euphoric mood *Rare* Anxiety *Additional post-marketing data* Frequency not known **Nervous system disorders** Paraesthesia in lower limbs *Very Common* Dizziness Headache *Common* Paraesthesia *Uncommon* Memory impairment *Rare* Eye disorders Visual impairment *Uncommon* Abnormal sensation in eye Visual disturbance *Rare* **Ear and labyrinth disorders** Tinnitus *Uncommon* Endocrine disorders Pituitary apoplexy** *Additional post-marketing data* Frequency not known **Cardiac disorders** Palpitations *Uncommon* QT prolongation* (see sections 4.4 and 4.5) *Additional post-marketing data* Frequency not known **Vascular disorders** Hot flush *Very Common* Hypertension *Common* Hypotension *Rare* **Respiratory, thoracic and mediastinal disorders** Dyspnoea Epistaxis *Uncommon* Orthopnoea *Rare* **Gastrointestinal disorders** Dry mouth Nausea *Common* Abdominal pain Constipation Diarrhoea Vomiting *Uncommon* Abdominal distension Dysgeusia Flatulence *Rare* **Skin and subcutaneous tissue disorders** Hyperhidrosis *Very Common* Acne Alopecia Erythema Pruritus Rash Urticaria *Uncommon* Blister Purpura *Rare* Angioneurotic oedema *Additional post-marketing data* Frequency not known **Musculoskeletal and connective tissue disorders** Back pain *Very Common* Musculoskeletal pain Pain in extremity *Common* Arthralgia Bone pain Muscle cramp Muscular weakness Myalgia *Uncommon* Joint stiffness Joint swelling Musculoskeletal stiffness Osteoarthritis *Rare* **Renal and urinary disorders** Nocturia Urinary retention *Uncommon* Urinary incontinence *Additional post-marketing data* Frequency not known **Reproductive system and breast disorders** Erectile dysfunction (including ejaculation failure, ejaculation disorder) *Very Common* Pelvic pain *Common* Gynaecomastia Breast pain Testicular atrophy Testicular pain *Uncommon* **General disorders and administration site conditions** Asthenia *Very Common* Injection site reaction (including erythema inflammation and pain) Oedema *Common* Lethargy Oedema peripheral Pain Rigors Somnolence *Uncommon* Chest pain Dysstasia Influenza-like illness Pyrexia *Rare* **Malaise** *Additional post-marketing data* Frequency not known **Investigations** Weight increased *Common* Alanine aminotransferase increased Aspartate aminotransferase increased Blood creatinine increased Blood pressure increased Blood urea increased Gamma-glutamyl transferase increased Weight decreased *Uncommon* Blood alkaline phosphatase increased *Rare* *This frequency is based on class-effect frequencies common for all GnRH agonists. **Reported following initial administration in patients with pituitary adenoma Triptorelin causes a transient increase in circulating testosterone levels within the first week after the initial injection of the sustained release formulation. With this initial increase in circulating testosterone levels, a small percentage of patients (≤5 %) may experience a temporary worsening of signs and symptoms of their prostate cancer (tumour flare), usually manifested by an increase in urinary symptoms (< 2%) and metastatic pain (5%), which can be managed symptomatically. These symptoms are transient and usually disappear in one to two weeks. Isolated cases of exacerbation of disease symptoms, either urethral obstruction or spinal cord compression by metastasis have occurred. Therefore, patients with metastatic vertebral lesions and/or with upper or lower urinary tract obstruction should be closely observed during the first few weeks of therapy (see section 4.4 Special warnings and precautions for use). The use of GnRH agonists to treat prostate cancer may be associated with increased bone loss and may lead to osteoporosis and increase the risk of bone fracture. This may also lead to an incorrect diagnosis of bone metastases. Patients receiving long-term treatment with GnRH analogue in combination with radiation therapy may have more side effects, mostly gastrointestinal and related to radiotherapy. **General tolerance in children** (see section 4.4) The frequency of the adverse reactions is classified as follows: very common (≥1/100); common (≥1/100 to <1/100); uncommon (≥1/1000, <1/100). **Eye disorders** Visual impairment *Uncommon* **Treatment related AEs** Visual disturbance *Additional post-marketing data* Frequency not known **Psychiatric disorders** Mood altered *Uncommon* **Treatment related AEs** Affect liability Depression Nervousness *Additional post-marketing data* Frequency not known **Reproductive system and breast disorders** Vaginal bleeding (including vaginal haemorrhage, withdrawal bleed, uterine haemorrhage, vaginal discharge, vaginal bleeding including spotting) *Very Common* **Treatment related AEs** Breast pain *Uncommon* **Treatment related AEs** Respiratory, thoracic and mediastinal disorders Epistaxis *Uncommon* **Treatment related AEs** Skin and subcutaneous tissue disorders Acne *Common* **Treatment related AEs** Pruritus Rash Urticaria *Uncommon* **Treatment related AEs** Angioneurotic oedema *Additional post-marketing data* Frequency not known **Vascular disorders** Hot flush *Common* **Treatment related AEs** Hypertension *Additional post-marketing data* Frequency not known * During post market experience convulsions have been reported in patients receiving GnRH analogues, including triptorelin. **General** Increased lymphocytes count has been reported with patients undergoing GnRH analogue treatment. This secondary lymphocytosis is apparently related to GnRH induced castration and seems to indicate that gonadal hormones are involved in thymic involution. **Reporting of suspected adverse reactions** Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to: Belgium Federal Agency for Medicines and Health Products www.afmps.be. Vigilance Division. Website: www.notifierneftindex.be, e-mail: adr@afmps.be. **MARKETING AUTHORISATION HOLDER** IPSEN nv Treurenberg 2 - 4 box 4 1000 Brussels Belgium **MARKETING AUTHORISATION NUMBER** BE362284 **DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION** Date of first authorisation: 09.10.2009 Date of renewal of the authorisation: 17.04.2019 **Method of dispensing** On medical prescription. **DATE OF REVISION OF THE TEXT** 10/2025. Ref: DKPP-BE-000221

PROGRAMME

Saturday 10 October 2026

08:30 Registration, welcome coffee & exhibition

09:00 Welcome + results

Toxicity and synergy in combined treatment strategies for...

Moderators: Alex De Caluwé (AZ Sint-Maarten / Institut J. Bordet) & François Lallemant (CHU Liège)

09:05 Head & Neck Cancer
Rachel Galot (UCLouvain)

09:25 Lung Cancer
Dirk De Ruysscher (Maastru)

09:45 Gastrointestinal Cancer
Ines Joye (Iridium Network)

10:05 Coffee break & exhibition

Moderators: Jean-François Daisne (Iridium Network) & Selma Ben Mustapha (UZ Brussel)

10:50 Breast Cancer
Alex De Caluwé (AZ Sint-Maarten / Institut J. Bordet)

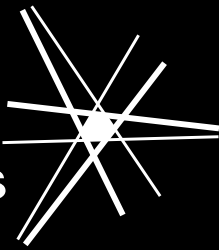
11:10 Combinations with cranial and extracranial stereotactic radiotherapy: what is allowed and what is forbidden?
Constance Golfier (Institut de Cancérologie de Lorraine)

11:40 Discussion

12:00 Closure

Visit our partners in the exhibition area (Atrium) during these moments.

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[CODING] ENERGY TO #END_CANCER;

At RaySearch Laboratories, we transform energy into intelligence.

Innovative yet refined radiotherapy software has always been at the core of our technology. Through advanced algorithms, we shape emergent therapeutical energy into optimized cancer care.

Our software solutions are more than just lines of code — they empower energy to fight cancer.

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RayCommand

A unified treatment control system

OUR SOLUTIONS

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Intelligent treatment planning

Liver Ablation

Image-guided planning for interventional radiology

DrugLog

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Planning and evaluation for pre-clinical research



RayPlan

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EXPLORE OUR SOLUTIONS

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Adaptive workflows are fully integrated into our software platforms, combining the powerful tools in RayStation®* — such as synthetic CT, dose tracking, and automated re-planning — with the orchestration capabilities of RayCare®*. At RaySearch, adaptive radiotherapy is no longer a concept — it's reality.
How? [Read more here.](#)

[AUTOMATING] ENERGY TO #END_CANCER;

RaySearch's automation suite** includes: a scripting interface and two AI-driven solutions for segmentation and treatment plan generation — all seamlessly integrated into RayStation®. By implementing these solutions, nearly 50% time savings on daily clinical tasks are reached. [See how here.](#)

[ADAPTING] ENERGY TO #END_CANCER;

RayCare® supports a growing ecosystem of treatment machines, with an ever-growing list of [interoperable systems](#) designed for today's clinical needs. RayStation® sits at the core of advanced treatment planning, enabling delivery across a wide spectrum of modalities — from [proton](#) and [ion therapy](#) to [tomotherapy](#).

RaySearch
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ONLINE ADAPTIVE UNLEASHED BY SOFTWARE

Keep your linac, choose:

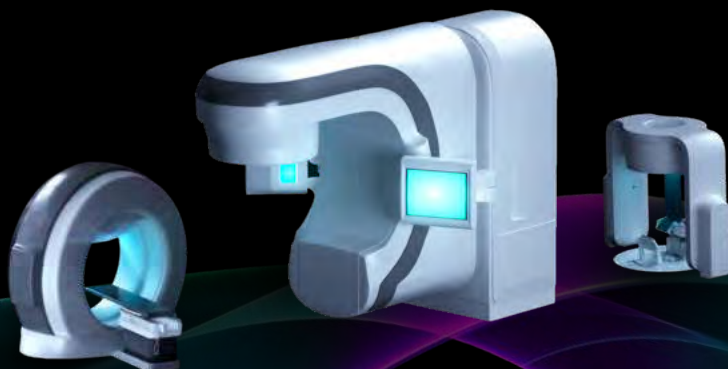


RayStation



RayCare

BOOK A DEMO



[ADAPTING] ENERGY
TO #END_CANCER;

Online Adaptive radiotherapy functionality is not cleared or approved for sale or clinical use in the United States or Canada. Availability in other markets is subject to applicable regulatory approvals and varies by region.

REIRRADIATION MADE SIMPLE



- Plan dose
- **Plan + prior treatment dose**
EQD2 Across modalities

BOOK A DEMO

[ADAPTING] ENERGY
TO #END_CANCER;

JUNIOR ABSTRACT 1

Assessing interinstitutional variability in delineation and treatment planning for pancreatic Stereotactic Body Radiotherapy: a pretrial benchmark analysis of the TORPEDO Study

Dr. Daan Stas · University of Antwerp, Iridium Network

BACKGROUND

Stereotactic body radiotherapy (SBRT) is increasingly used in the management of locally advanced pancreatic cancer (LAPC). Interinstitutional variability in target delineation and treatment planning may affect treatment quality and clinical trial outcomes. We evaluated the variability in target delineation and treatment planning among centres during the pretrial benchmark phase of the TORPEDO study, a multicentre, randomised phase II trial investigating the addition of SBRT to standard chemotherapy in patients with inoperable non-metastatic pancreatic adenocarcinoma.

METHODS

Ten centres completed a benchmark contouring case and nine completed the SBRT plan. Submitted target volumes and organs at risk (OARs) were compared with a reference contour, which served as the gold standard, and evaluated qualitatively by two experienced radiation oncologists and quantitatively using volumetric, overlap-based, and distance-based metrics.

Dosimetric parameters and dose-volume histograms were analysed to assess adherence to treatment-planning requirements.

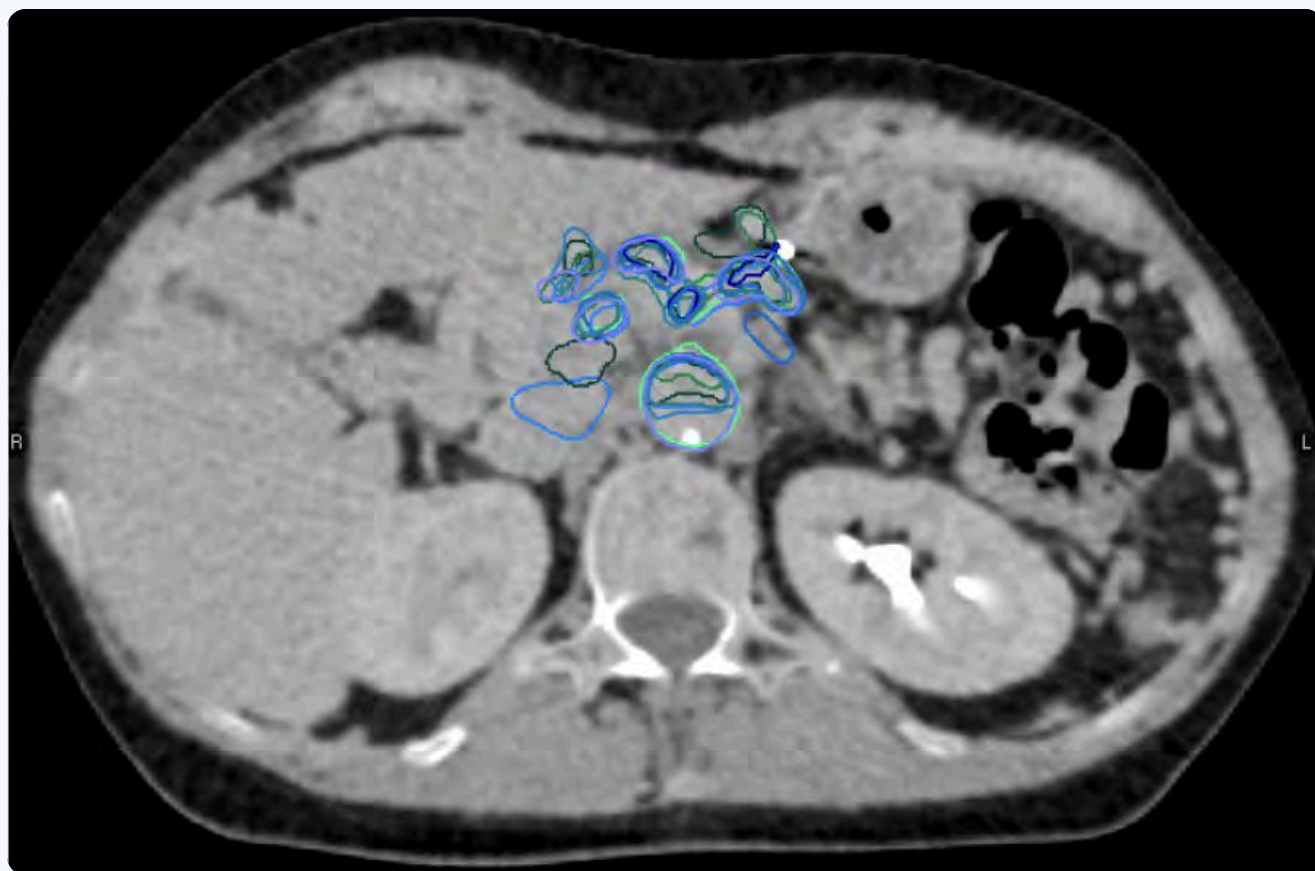
RESULTS

Among target volumes, 80.7% of delineations were per protocol, with 10.5% and 8.7% showing minor and major variations, respectively. OAR delineation showed 73.3% per-protocol compliance, with 22.2% minor and 4.4% major variations. Major deviations were uncommon, but mainly involved the tumour-vessel interface, PTV evaluation structure, small bowel, great vessels, and common bile duct. Quantitative analysis demonstrated moderate agreement for target volumes, with mean Dice similarity coefficients of 0.70 and 0.71 for PTV40 and PTV40_EVAL, respectively. Agreement was lower for smaller structures, including the common bile duct and vessel contours. Treatment planning demonstrated limited interinstitutional variability, with few major protocol deviations and substantial concordance of dose-volume histograms.

CONCLUSION

The benchmarking exercise demonstrated that target and OAR delineation and SBRT planning for LAPC remain challenging, with few major protocol deviations, but a substantial number of minor variations. As part of the QA programme, this benchmark exercise provides an important measure to identify and reduce interinstitutional variability and improve adherence to the radiotherapy protocol.

JUNIOR ABSTRACT 1 · FIGURE

Figure 1

The tumour-vessel interface delineated by the different centres which completed the contouring part of the pre-trial benchmark case.



The AIO Solution 3.0

One system for all positioning and immobilization needs



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JUNIOR ABSTRACT 2

Long-term recurrence patterns in rectal cancer after neoadjuvant therapy: 25 years of real-world data

Dr. Pieter Maerten · KU Leuven, UZ Leuven

BACKGROUND

The management of locally advanced rectal cancer has significantly evolved over the past 25 years, most recently with the adoption of total neoadjuvant therapy (TNT). Nevertheless, optimal treatment selection for individual patients remains challenging. This study evaluated recurrence patterns in rectal cancer to improve risk stratification and guide neoadjuvant treatment decisions in the TNT era.

METHODS

We conducted a prospective cohort study including 850 rectal cancer patients treated with neoadjuvant radio- and chemotherapy over a 25-year period.

FINDINGS

After a median follow-up of 12 years, 5-year overall survival (OS) and disease-free survival (DFS) were 86.8% and 75.5%. Recurrence occurred in 167 patients

(19.6%), including 31 (3.6%) with locoregional recurrence (LRR), 158 (18.6%) with distant metastases (DM) and 22 (2.6%) with both.

Five-year recurrence-free survival (RFS), DM-free survival (DMFS) and LRR-free survival (LRFS) were 76.9%, 77.8% and 85.3%. Mesorectal fascia involvement ($p = 0.006$) and extra-mural vascular invasion ($p = 0.028$) were associated with recurrence on univariable analysis, although their impact diminished after adjusting for neoadjuvant treatment. Independent predictors of DM were lymphovascular invasion ($p < 0.001$), perineural invasion ($p = 0.004$), positive circumferential resection margin ($p = 0.046$) and higher lymph node ratio (LN-ratio) ($p < 0.001$). Tumor diameter ($p = 0.025$) and LN-ratio ($p = 0.047$) independently predicted LRR. Early recurrence was associated with worse OS, although post-recurrence survival did not differ significantly.

CONCLUSION

Histopathological features and tumor response to neoadjuvant therapy are strong predictors of recurrence risk in rectal cancer. Identifying reliable baseline biomarkers of treatment response is essential to refine patient risk stratification and personalize neoadjuvant treatment strategies in the TNT era.

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HONORARY MEMBER LECTURE

Prof. Dr. Eric Deutsch

MD, PhD · Radiation Oncologist

Gustave Roussy Cancer Campus · Paris-Saclay University

LECTURE · FRIDAY 16:05

General introduction on the advantages and risks of combination therapy in the pre-clinical setting



BIOGRAPHY

Eric Deutsch, MD, PhD, is Full Professor of Radiation Oncology at Paris-Saclay University, Director of the Inserm UMR1030 “Molecular Radiotherapy and Innovative Therapeutics” research unit, and Head of the Department of Radiation Oncology at Gustave Roussy Cancer Campus, Villejuif, France.

Under his leadership, Prof. Deutsch oversees a team of more than 150 clinicians, researchers and support staff, integrating clinical excellence with cutting-edge translational research and early-phase clinical trials. He has developed a research axis focused on the personalization of radiotherapy and immunotherapy through artificial intelligence-driven approaches.

As principal investigator, he has led several first-in-human clinical trials evaluating innovative therapeutic agents, including immunomodulatory compounds combined with radiotherapy. He is also a board member of the Gustave Roussy Technology Transfer Office.

His research focuses on mechanisms of cell death, HPV-related tumors and tumor-stroma interactions, with a strong emphasis on tumor immunology.

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HONORARY MEMBER LECTURE

Prof. Dr. Dirk De Ruyscher

MD, PhD · Radiation Oncologist

Maastricht University Medical Center & Erasmus MC



LECTURE · FRIDAY 14:55

General introduction on the advantages and risks of combination therapy in the clinical setting

BIOGRAPHY

Dr. De Ruyscher earned his medical degree at the University of Leuven in 1986, became a radiation oncologist there in 1991 and obtained his PhD in 1992 on the influence of radiotherapy on immunity.

He is currently full Professor of Radiation Oncology / Respiratory Oncology at Maastricht University Medical Center and Erasmus MC Rotterdam. He heads Maastricht Clinical Research and chairs the EORTC Lung Cancer Group / Oligometastatic and New Development Group.

His research spans individualized radiotherapy, combined treatments, proton therapy, radiogenomics, immunotherapy and artificial intelligence. He has served as lead PI on numerous phase I, II and III trials and coordinates Maastricht's biobank project, which has included around 10,000 patients for radiogenomic studies.

He also leads a laboratory investigating predictive tests on tumour replicas to identify optimal anti-cancer drugs for individual patients. He has authored more than 550 peer-reviewed papers and book chapters.

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DÉNOMINATION DU MÉDICAMENT Erleada 240 mg comprimés
COMPOSITION QUALITATIVE ET QUANTITATIVE

Chaque comprimé pelliculé contient 240 mg d'apalutamide. **FORME**

PHARMACEUTIQUE Comprimé pelliculé (comprimé). Comprimé

pelliculé gris bleuté à gris, de forme ovale (21 mm de long x 10 mm

de large), avec l'inscription « E240 » imprimée sur une face. **Indications**

thérapeutiques Erleada est indiqué : - dans le traitement des hommes adultes

atteints d'un cancer de la prostate résistant à la castration non métastatique (nmCRPC)

avec un risque élevé de développer une maladie métastatique. - dans le traitement des hommes

adultes atteints d'un cancer de la prostate métastatique hormonosensible (mHSPC) en association avec

un traitement par suppression androgénique (ADT). **Posologie et mode d'administration** Le traitement par

apalutamide doit être instauré et supervisé par un médecin spécialiste expérimenté dans le traitement du cancer de

la prostate. **Posologie** La dose recommandée est de 240 mg (un comprimé de 240 mg) en une seule prise quotidienne par

voie orale. La castration médicale par analogue de l'hormone de libération des gonadotrophines (GnRH) doit être maintenue

pendant la durée du traitement chez les patients n'ayant pas subi de castration chirurgicale. Si le patient oublie de prendre une dose,

il doit la prendre dès que possible le jour même, et reprendre le schéma normal le lendemain. Le patient ne doit pas prendre de comprimés

supplémentaires pour compenser la dose oubliée. Si une toxicité de grade ≥ 3 ou un effet indésirable intolérable est éprouvé par un patient, plutôt

que d'arrêter définitivement le traitement, l'administration doit être suspendue jusqu'à amélioration des symptômes à un grade ≤ 1 ou au grade d'origine,

puis doit être reprise à la même dose ou à une dose réduite (180 mg ou 120 mg), si nécessaire. Pour connaître les effets indésirables les plus fréquents.

Populations particulières **Sujets âgés** Aucun ajustement posologique n'est nécessaire chez les patients âgés. **Insuffisance rénale** Aucun ajustement posologique n'est

nécessaire chez les patients présentant une insuffisance rénale légère ou modérée. La prudence est recommandée chez les patients présentant une insuffisance rénale

sévère car l'apalutamide n'a pas été étudié dans cette population. Si le traitement est initié, les patients doivent être surveillés pour les effets indésirables mentionnés à la rubrique

Effets indésirables et la dose réduite comme indiqué à la rubrique Posologie et mode d'administration. **Insuffisance hépatique** Aucun ajustement posologique n'est nécessaire chez les

patients présentant une insuffisance hépatique légère à modérée (classes A et B de Child-Pugh, respectivement) à l'instauration du traitement. Chez les patients présentant une insuffisance

hépatique sévère (classe C de Child-Pugh), la dose recommandée est de 120 mg (deux comprimés de 60 mg) en une prise quotidienne par voie orale. **Population pédiatrique** Il n'existe pas d'utilisation

justifiée de l'apalutamide dans la population pédiatrique. **Mode d'administration** Voie orale. Le comprimé doit être avalé entier afin de garantir la prise de la dose complète prévue. Le comprimé ne doit pas

être écrasé ou coupé. Le comprimé peut être pris pendant ou en dehors des repas. **Prise d'Erleada avec une boisson non gazeuse ou un aliment de consistance molle** Pour les patients qui ne peuvent pas avaler le

comprimé entier, Erleada peut être dispersé dans de l'eau non gazeuse, puis mélangé à l'une des boissons non gazeuses ou à l'un des aliments de consistance molle suivants : jus d'orange, thé vert, compote de pommes,

yaourt à boire ou un volume d'eau supplémentaire, comme suit : 1. Placer le comprimé entier d'Erleada 240 mg dans une tasse. Ne pas écraser ou couper le comprimé. 2. Ajouter environ 10 mL (2 cuillères à café) d'eau non gazeuse afin

de s'assurer que le comprimé est complètement dans l'eau. 3. Attendre 2 minutes jusqu'à ce que le comprimé soit morcelé et dispersé, puis remuer le mélange. 4. Ajouter 30 mL (6 cuillères à café ou 2 cuillères à soupe) d'une des boissons non

gazeuses ou d'un des aliments de consistance molle suivants : jus d'orange, thé vert, compote de pommes, yaourt à boire ou volume d'eau supplémentaire, et remuer le mélange. 5. Avaler le mélange immédiatement. 6. Rincer la tasse avec suffisamment

d'eau afin de s'assurer que toute la dose a été prise et la boire immédiatement. 7. Ne pas conserver le mélange médicament/aliment pour une utilisation ultérieure. **Administration par sonde de nutrition nasogastrique** Le comprimé d'Erleada 240 mg peut également

être administré par une sonde de nutrition nasogastrique (sonde NG 8 CH ou plus, comme suit : 1. Placer le comprimé entier d'Erleada 240 mg dans le corps d'une seringue (utiliser une seringue d'au moins 20 mL) et remplir 10 mL d'eau non gazeuse dans la seringue. 2.

Attendre 10 minutes, puis agiter vigoureusement pour disperser complètement le contenu. 3. Administrer immédiatement par la sonde de nutrition nasogastrique. 4. Remplir à nouveau la seringue d'eau non gazeuse et administrer. Répéter l'opération jusqu'à ce qu'il ne reste

plus aucun résidu de comprimé dans la seringue ou la sonde de nutrition. **Contre-indications** Hypersensibilité à la substance active ou à l'un des excipients. Femmes enceintes ou susceptibles de l'être. **Effets indésirables** **Résumé du profil de sécurité** Les effets indésirables

les plus fréquents sont : fatigue (26 %), éruption cutanée (26 % tous grades confondus et 6 % de grade 3 ou 4), hypertension (22 %), bouffée de chaleur (18 %), arthralgie (17 %), diarrhée (16 %), chute (13 %) et poids diminué (13 %). Les autres effets indésirables importants

incluent fractures (11 %), appétit diminué (11 %) et hypothyroïdie (8 %). **Tableau récapitulatif des effets indésirables** Les effets indésirables rapportés pendant les études cliniques et/ou post-commercialisation sont classés ci-dessous par catégorie de fréquence. Les catégories de

fréquence sont définies de la manière suivante : très fréquent ($\geq 1/10$); fréquent ($\geq 1/100$ à $< 1/10$); peu fréquent ($\geq 1/1000$ à $< 1/100$); rare ($< 1/1000$ à $< 1/10000$); très rare ($< 1/10000$) et fréquence indéterminée (ne peut être estimée sur la base des données disponibles). Dans

chaque groupe de fréquence, les effets indésirables sont présentés par ordre décroissant de gravité. **Tableau 1 : Effets indésirables : Classe de Systèmes d'Organes** : Effet indésirable et fréquence **Affections hématoLOGIQUES et du système lymphatique** : Fréquent : neutropénie ;

Fréquence indéterminée : agranulocytose **Affections endocriniennes** : Fréquent : hypothyroïdie **Troubles du métabolisme et de la nutrition** : Très fréquent : appétit diminué ; Fréquent : hypercholestérolémie, hypertriglycéridémie **Affections du système nerveux** : Fréquent :

dyssgueusie, anomalies ischémiques du système cérébrovasculaire¹ ; Peu fréquent : convulsions², syndrome des jambes sans repos **Affections cardiaques** : Fréquent : cardiopathie ischémique³ ; Fréquence indéterminée : Allongement de l'intervalle QT **Affections vasculaires** :

Très fréquent : bouffée de chaleur, hypertension **Affections respiratoires, thoraciques et médiastinales** : Fréquence indéterminée : pneumopathie interstitielle diffuse⁴ **Affections gastrointestinales** : Très fréquent : diarrhée **Affections de la peau et du tissu sous-cutané** :

Très fréquent : éruption cutanée⁵ ; Fréquent : prurit, alopecie ; Peu fréquent : éruption lichénoïde ; Fréquence indéterminée : réaction médicamenteuse avec éosinophilie et symptômes systémiques (syndrome DRESS)⁶, syndrome de Stevens-Johnson/nécrolyse épidermique toxique

(SJS/NET)⁷ **Affections musculosquelettiques et du tissu conjonctif** : Très fréquent : fractures⁸, arthralgie ; Fréquent : spasme musculaire **Troubles généraux et anomalies au site d'administration** : Très fréquent : fatigue **Investigations** : Très fréquent : perte de poids **Lésions,**

intoxications et complications d'interventions : Très fréquent : chutes. ¹Inclut hypothyroïdie, augmentation de la thyroïdostimuline sanguine, diminution de la thyroxine, thyroïdite auto-immune, diminution de la thyroxine libre, diminution de la triiodothyronine ²Inclut accident ischémique

transitoire, accident cérébrovasculaire, trouble cérébrovasculaire, accident ischémique cérébral, artériosclérose carotidienne, sténose carotidienne, hémiparésie, infarctus lacunaire, accident vasculaire cérébral lacunaire, infarctus cérébral thrombotique, encéphalopathie vasculaire,

infarctus cérébelleux, infarctus cérébral et ischémie cérébrale ³Inclut morsure de langue ⁴Inclut angine de poitrine, angor instable, infarctus du myocarde, infarctus du myocarde aigu, occlusion artérielle coronaire, sténose artérielle coronaire, syndrome coronaire aigu, athérosclérose

de l'artère coronaire, épreuve d'effort cardiaque anormale, tropinone augmentée, ischémie myocardique ⁵Voir Résumé des caractéristiques du produit ⁶Voir « Eruption cutanée » à la rubrique « Description d'une sélection d'effets indésirables » ⁷Inclut fracture des côtes, fracture

vertébrale lombaire, fracture rachidienne par compression, fracture rachidienne, fracture du pied, fracture de la hanche, fracture de l'humérus, fracture vertébrale thoracique, fracture du membre supérieur, fracture du sacrum, fracture de la main, fracture du pubis, fracture acétabulaire,

fracture de la cheville, fracture par compression, fracture du cartilage costal, fracture des os du visage, fracture du membre inférieur, fracture ostéoporotique, fracture du poignet, fracture avulsion, fracture du péroné, fracture du coccyx, fracture du bassin, fracture du radius, fracture

du sternum, fracture de fatigue, fracture de stress, fracture traumatique, fracture des vertèbres cervicales, fracture du col du fémur, fracture du tibia. Voir ci-dessous. **Description d'une sélection d'effets indésirables** Eruption cutanée L'éruption cutanée associée à l'apalutamide était

le plus souvent décrite comme maculaire ou maculopapuleuse. L'éruption cutanée inclut : éruption, éruption maculopapuleuse, éruption généralisée, urticaire, éruption prurigineuse, éruption maculaire, conjonctivite, érythème polymorphe, éruption papuleuse, desquamation cutanée,

éruption géinitale, éruption érythémateuse, stomatite, éruption d'origine médicamenteuse, ulcération buccale, éruption pustuleuse, cloque, papule, pemphigoïde bulleuse, érosion cutanée, dermatite et éruption vésiculaire. Des effets indésirables d'éruption cutanée ont été rapportés chez

26 % des patients traités par apalutamide. Des éruptions cutanées de grade 3 (définies comme couvrant une surface corporelle [SC] ≥ 30 %) ont été rapportées chez 6 % des patients traités par apalutamide et 3 % des patients recevant le placebo. Le nombre de jours médian avant l'apparition de l'éruption cutanée était de

83 jours. Chez soixante-dix-huit pourcents des patients, l'éruption s'est résolue dans un délai médian de 78 jours. Les médicaments utilisés ont inclus les corticostéroïdes topiques, les antihistaminiques oraux et 19 % des patients ont reçu des corticostéroïdes systémiques. Parmi les patients

ayant présenté une éruption cutanée, le traitement a été interrompu chez 28 % d'entre eux et la dose réduite chez 14 % d'entre eux. L'éruption cutanée est réapparue chez 59 % des patients ayant eu une interruption de traitement. Le traitement par apalutamide a été arrêté chez 7

% des patients ayant présenté une éruption cutanée. **Chutes et fractures** Dans l'étude ARN-509-003, des fractures ont été rapportées chez 11,7 % des patients traités par apalutamide et 6,5 % des patients traités par placebo. La moitié des patients a subi une chute dans les 7 jours

précédant l'événement de fracture dans les deux groupes de traitement. Des chutes ont été rapportées chez 15,6 % des patients traités par apalutamide versus 9,0 % des patients recevant le placebo. **Cardiopathie ischémique et anomalies ischémiques du système cérébrovasculaire**

Dans une étude randomisée chez des patients atteints de nmCRPC (SPARTAN), une cardiopathie ischémique est survenue chez 4 % des patients traités par apalutamide et 3 % des patients ayant reçu le placebo. Dans une étude randomisée chez des patients atteints de mHSPC

(TITAN), une cardiopathie ischémique est survenue chez 4 % des patients traités par apalutamide et de 11,5 % pour le placebo, des anomalies ischémiques du système cérébrovasculaire sont survenues chez 4 % des patients traités par apalutamide et 1 %

des patients ayant reçu le placebo (voir ci-dessus). Dans l'étude TITAN, des anomalies ischémiques du système cérébrovasculaire sont survenues en une proportion similaire chez les patients des groupes apalutamide (1,5 %) et placebo (1,5 %). Au cours des études SPARTAN et TITAN,

2 patients traités par apalutamide (0,2 %) sont décédés d'une anomalie ischémique du système cérébrovasculaire et aucun patient ayant reçu le placebo n'a été décédé des suites de cette anomalie. **Hypothyroïdie** Une hypothyroïdie a été rapportée chez 8 % des patients traités par

apalutamide et 2 % des patients sous placebo, selon les évaluations de la thyroïdostimuline (TSH) tous les 4 mois. Aucun événement indésirable de grade 3 ou 4 n'a été observé. Une hypothyroïdie s'est produite chez 30 % des patients recevant déjà une hormonothérapie thyroïdienne de

substitution dans le bras apalutamide et chez 3 % des patients dans le bras placebo. Chez les patients ne recevant pas d'hormonothérapie thyroïdienne de substitution, une hypothyroïdie s'est produite chez 7 % des patients traités par apalutamide et chez 2 % des patients recevant le

placebo. L'hormonothérapie thyroïdienne de substitution, lorsqu'elle est cliniquement indiquée, doit être instaurée ou ajustée à la dose. **Déclaration des effets indésirables suspectés** La déclaration des effets indésirables suspectés après autorisation du médicament est

importante. Elle permet une surveillance continue du rapport bénéfice/risque du médicament. Les professionnels de santé déclarent tout effet indésirable suspecté via : **Belgique** Agence fédérale des médicaments et des produits de santé www.afmps.be Division Vigilance

Site internet : www.notifieruneffetindesirable.be E-mail : adr@agg-afmps.be **Luxembourg** Centre Régional de Pharmacovigilance de Nancy ou Division de la pharmacie et des médicaments de la Direction de la santé Site internet : www.guichet.lu/pharmacovigilance **TITULAIRE DE**

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