

Press release

# Give some **PINK** to **SE**vri**eN**



**Breast cancer, one of the best treated... or not!**  
When the price of your life requires you to raise a colossal amount of money to hope for a remission.

[www.givesomepinktosevrien.be](http://www.givesomepinktosevrien.be)



**Breast cancer, one of the best treated... or not!**  
When the price of your life requires you to raise a colossal amount of money to hope for a remission.



### **The story of Sevrien, a fighter, Emy's mother and Boris' partner**

Sevrien is a friend, a sister, a colleague that everyone would like to have. Her infectious laughter is matched only by the efficiency she puts into her work every day to help others. Although Sevrien lives in Flanders, she has been working for 16 years at MIRENA, the regional mission for employment in Namur. A job in which she gives herself without counting to help job seekers to find a job. Sevrien is also the dynamism and the joy of life of zumba, but above all she is a 37-year-old mother who gives us an incredible example of fighting spirit.

In November 2020, Sevrien felt a suspicious swollen lymph node under her armpit. She consulted the doctor who prescribed tests. No lump in the breast on palpation, nothing on the mammogram or ultrasound. But the doubt is there. An MRI and a biopsy are performed. The verdict was in, it was triple negative breast cancer (see below). Faced with this diagnosis, Sevrien had to be directly taken care of. She was forced to stop working and gave up her zumba classes. She focused all her energy on fighting the disease. As soon as the diagnosis was announced, all her colleagues and friends mobilized and were present at each stage of the treatment with messages of support, videos, sending cards and parcels... For several months,

she underwent invasive chemotherapy treatments with heavy side effects...

In the spring, she saw her oncologist. The news was good! « Madam, there is nothing left in your breast, you are in remission, if I may say so ». A few glimpse of hope and the euphoria linked to this verdict gave Sevrien a boost... A total mastectomy and the removal of lymph nodes followed. After analysis, the oncologist's speech became darker. « The chemotherapy worked on the breast, but not on the lymph nodes ».

The result of the CT scan that followed was dramatic: there were bone metastases... The prognosis was vital, it was an emergency. The treatment strategy was adapted: Sevrien began an immunotherapy treatment. After three months of this new treatment, Sevrien had a first check-up. The cancer is still progressing. It has metastasized to the lungs. The health care team that had accompanied Sevrien from the beginning was at a dead end: only palliative care was offered.

Refusing to accept this, Sevrien, supported by the armada that has been with her since the beginning, is exploring other options. She knows that a treatment adapted to her pathology exists in Germany and that it will be more effective if it is preceded by Trodelvy®, medication that is not available in Belgium. Trodelvy® has two advantages: it slows down the progression of the cancer and increases the effectiveness of the German therapy.

She initiated the first contacts with Germany. Sevrien then met a new team of doctors at the forefront of this pathology who contacted the German team in order to define the best treatment path. At the same time, she moved heaven and earth to have access to Trodelvy® and put together files to be able to benefit from the intervention of the health insurance. Although reimbursement for Trodelvy® is possible under very restrictive conditions, the cost of this drug combined with the treatment available in Germany costs at least €200,000.

In order to define the best therapeutic strategy, the new medical team is performing a new biopsy, the results of which are still pending. One thing is certain, the German treatment is a must to keep the hope for Sevrien of seeing Emy grow up.



## Give some PINK to SEvriEN

*Together, we can defy the unacceptable.*

Sevrien's willpower, courage and determination inspired those around her and gave birth to a collective will to do everything possible to ensure that money is not a barrier to access to treatment. In one weekend, the communication, the website, and the social networks relayed her fight under the name of: [Givesomepinktosevrien](#). It is the movement created to allow her to benefit from the last chance treatment. The one that could stabilize the disease and offer her a hope of remission. A chance also for her to see her little Emy grow up. And for Emy, the chance to grow up with her mother. For Boris, it's a chance to continue to be supported by his incredible love, which he supports without fail.

Very quickly, initiatives were launched to raise funds. Since the end of September, her relatives have raised awareness among all their networks. They have sold balloons, waffles, pens, badges, handmade jewellery and keychains, walked for miles, danced to the sound of Zumba, cooked pancakes, made macramé, ... and this is just the beginning. A concert, a beer sale, quiz nights, Think-Pink actions, a bike ride and many other activities are in preparation!

**In a few days, thanks to an incredible amount of solidarity and generosity, nearly 35,000€ have been raised.** Family, friends and colleagues are mobilizing on both sides of the language border.

In order to manage this fundraising in all transparency, the ASBL «**Give some Pink to Sevrien**» was created. This association also aims to put the spotlight on triple negative cancer. If today Sevrien must concentrate on her fight, she hopes one day to be able to help other triple-negative breast cancer victims and to join French groups such as RoseUp or the Triplettes. She hopes that her experience can contribute to ease access to free care.

Indeed, there are far too many patients like Sevrien. If she is supported by the love of her family, friends and colleagues, other triplets are not as surrounded and simply end up stopping the fight. Alone, it is difficult to keep hope.

On our social networks and our website, we call upon the creativity of people

## Give some PINK to SEvrien

touched by Sevrien's fight to help us carry out actions and raise funds. If everyone makes a gesture to the extent of what they can, Sevrien will have a chance to see Emy grow up with Boris. Beyond the payments which are essential, any action which can help to collect funds is encouraged.

It is vital for Sevrien, Emy, Boris

*Links to the fundraiser, our site and our networks:*

---



<https://gofund.me/684ee68f>

[www.givesomepinktosevrien.be](http://www.givesomepinktosevrien.be)



<https://www.facebook.com/givesomepinktoSevrien/>

<https://www.instagram.com/givesomepinktosevrien/>

To be clearer:

## What is triple negative breast cancer (TNBC)?

Generally, more aggressive in nature than the others, it represents about 10 to 15%<sup>[1]</sup> of breast cancers. It is thought to affect women under 40 years of age who are not menopausal. It is called «triple negative» because while most breast cancers express one or two of the three major growth receptors present in the breast (estrogen receptor, progesterone receptor and a last one called human epidermal growth factor (HER2) which are targets for specific treatments that block these receptors), TNBC does not have any of these receptors, hence its name triple negative breast cancer (TNBC).

As with all breast cancers, screening should be based on several examinations: physical examination and mammography (for screening or when an abnormality is palpated). Personal and family history is also assessed. These first examinations can be completed, in case of abnormality, by complementary examinations: breast ultrasound with biopsy, blood test, magnetic resonance imaging (MRI) which allows to evaluate more specifically the breast tissue... But it is with the biopsy of the tumor that the diagnosis of breast cancer and its characterization as triple negative is made.

### *Treatment modalities*

Initial management of triple-negative breast cancer is based on several modalities: surgery, radiation therapy, chemotherapy, and immunotherapy, mostly in clinical trials. Because TNBC does not express hormone receptors or HER2 receptors, patients with this type of cancer cannot receive hormonal therapy that blocks estrogen receptors or targeted anti-HER2 therapy.

About half of triple-negative breast cancers respond well to chemotherapy. For the other half, the disease becomes more complicated to treat because it is resistant to chemotherapy. The cancer then develops metastases on the bone, lungs, liver and finally in the brain. These patients affected by metastatic triple-negative breast cancer then find themselves in a therapeutic impasse because chemotherapy is no longer effective.

### *Trodelvy®, a promising therapeutic option*

A treatment using antibodies in combination with chemotherapy exists. It is Trodelvy® from the Gilead laboratory. Previously reserved for a limited number of patients with triple-negative metastatic breast cancer, early access to this treatment has been authorized in France since September 2, 2021 by the French National Authority for Health (HAS) under a temporary authorization for registered use (ATU).

The process of bringing an innovative medication on the market, from basic research to marketing authorization (MA) and the decision to be reimbursed by the health insurance system, takes several years. An early access authorization allows people in urgent need to benefit from a medication without waiting for it to go through the final stages. This is the solution when there is no other appropriate treatment for the patient and his or her state of health does not permit waiting. It is the case with Sevrien and many triplets.

Patients treated with Trodelvy® have slower cancer progression than patients treated with chemotherapy alone. They live longer than if they had received chemotherapy alone. In addition, more than a third of patients have a reduction in their cancer mass (35% versus 5% with chemotherapy)<sup>[2]</sup>. This treatment therefore represents a very important hope for all people with triple-negative breast cancer at a metastatic stage.

### *And in Belgium?*

Unfortunately, Trodelvy® is not yet available in Belgium. In addition to fighting the disease, patients have to struggle to get access to this new treatment in Germany or France, the price of which is exorbitant. So, the patients and their relatives are setting up fundraising campaigns. They hope to collect the necessary funds to be able to benefit from treatments that have been proven and approved in neighboring countries and thus increase their life expectancy.

Sevrien is moving heaven and earth to have access to Trodelvy at first and then to the promising immuno-vaccino therapy<sup>[3]</sup> in Germany .

Immunotherapy is positioned as an alternative to chemotherapy. This therapeutic approach, which is still recent, is already applied to a small number of cancers but is developing rapidly.

Unlike cancer chemotherapy, cancer immunotherapy does not rely on chemical substances to eliminate cells that have become cancerous. It involves mobilizing the immune system and focusing its action against cells that are proliferating uncontrollably.

Cancer immunotherapy focuses on all the immune cells involved in recognizing abnormal cells and destroying them.

When a cell becomes cancerous, it expresses markers on its surface that tell the immune system that it has become malignant. These are called tumor antigens. Unfortunately, as the cells evolve, these antigens are no longer expressed and the cells escape the vigilance of the immune system.

The goal is to «turn on» and educate the immune system to attack these abnormal

cells. To do this, there are several strategies, including therapeutic vaccines. The goal of this vaccination is to specifically direct immunity against the cancer cells. Each vaccine is personalized and adapted to the patient's cancer. It is the individualization of this targeted therapy according to each patient's case that explains its cost.

*Scientific part of the press kit reviewed by oncologist Emmanuelle Dochy, MD*

## Annexe :



## RÉFORME DE L'ACCÈS DÉROGATOIRE AUX MÉDICAMENTS

Juillet 2021



### L'accès dérogatoire, c'est quoi ?

En France, depuis plus de 20 ans, un **patient en situation d'impasse thérapeutique peut bénéficier d'un médicament non autorisé dans l'indication concernée.**

#### Plusieurs conditions doivent être réunies

- Maladie grave, rare ou invalidante.
- Absence de traitement approprié.
- Traitement ne pouvant être différé.
- Efficacité et sécurité du médicament fortement présumées.



### Pourquoi une réforme ?

- Pour **simplifier** les procédures.
- Pour **accélérer** les délais d'accès au traitement pour les patients.
- Pour **approfondir** les connaissances scientifiques par le renforcement du recueil des données cliniques et en impliquant les patients.



### En quoi consiste la réforme ?

À partir du 1<sup>er</sup> juillet 2021, **2 régimes d'autorisation** viennent remplacer les 6 existants



#### ACCÈS COMPASSIONNEL

Remplace les ATUn et RTU\*

- Pour les médicaments non destinés à être commercialisés dans l'indication concernée.
- Absence de développement en cours/prévu.
- Pas de démarche en vue d'une AMM.

Sur initiative de l'**ansm**, à la demande de professionnels de santé, des ministres ou sur signalements

Évaluation et décision de l'**ansm**

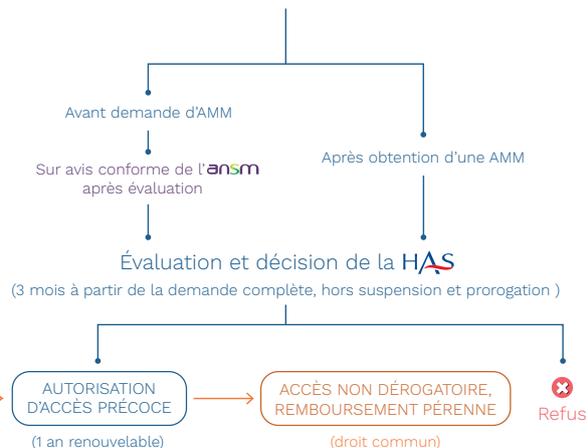


#### ACCÈS PRÉCOCE

Remplace les ATUc, ATUei, post-ATU, PECT\*\*

- Pour les médicaments destinés à être commercialisés dans l'indication concernée.
- Médicaments présumés innovants.
- Données cliniques disponibles ou en cours de recueil.

Sur demande du laboratoire



Arrêt possible en fonction des nouvelles données disponibles

\* L'autorisation temporaire d'utilisation nominative (ATUn) devient autorisation d'accès compassionnel. La recommandation temporaire d'utilisation (RTU) devient cadre de prescription compassionnelle et répond à d'autres conditions que celles de l'AC et l'AP.  
 \*\* Autorisation temporaire d'utilisation de cohorte. Autorisation temporaire d'utilisation d'extension d'indication. Post-Autorisation temporaire d'utilisation. Prise en charge temporaire.

Sources :

---

<https://www.cancer.be/les-cancers-types-de-cancers-liste-z/cancer-du-sein>

<http://www.cancerdusein.org/>

<https://www.e-cancer.fr/>

<https://www.bordet.be/fr/cancers-sein>

<https://www.gustaveroussy.fr/fr/cancer-sein/traitement>

<https://www.estrepublicain.fr/sante/2020/11/26/cancer-du-sein-triple-negatif-metastatique-l-immunotherapie-ciblee-peut-etre-une-chance-de-survie>

<https://sante.journaldesfemmes.fr/fiches-maladies/2548466-cancer-du-sein-triple-negatif-definition-symptomes-causes-traitement/>

<https://www.mcgill.ca/newsroom/fr/channels/news/cancer-du-sein-triple-negatif-une-nouvelle-etude-ouvre-la-voie-un-traitement-novateur-331318>

<https://www.roche.fr/fr/patients/info-patients-cancer/comprendre-cancer/cancer-du-sein-triple-negatifs.html>

<https://www.monreseau-cancerdusein.com/actualites/mobilisationtripletpettes-sans-traitement-novateur-des-milliers-de-femmes-condam>

<https://www.rose-up.fr/magazine/cancer-sein-triple-negatif-metastatique-trodelvy-traitement-innovant-trodelvy/>

<https://www.rose-up.fr/magazine/cancer-sein-triple-negatif-trodelvy-mobilisation-collectif-tripletpettes/>

<https://www.rose-up.fr/magazine/trodelvy-cancer-sein-triple-negatif-metastatique-probleme-appvisionnement/>

<https://www.rtl.be/info/vous/temoignages/le-cancer-du-sein-triple-negatif-de-nouveaux-traitements-donnent-de-l-espoir-mais-se-font-attendre-1312006.aspx>

<https://www.gilead.com/news-and-press/press-room/press-releases/2021/6/trodelvy-demonstrates-superior-outcomes-to-standard-of-care-in-second-line-treatment-of-metastatic-triple-negative-breast-cancer-in-phase-3-ascent-st>

[https://www.has-sante.fr/jcms/p\\_3284628/fr/cancer-du-sein-triple-negatif-la-has-autorise-le-trodelvy-en-acces-precoce](https://www.has-sante.fr/jcms/p_3284628/fr/cancer-du-sein-triple-negatif-la-has-autorise-le-trodelvy-en-acces-precoce)

[https://www.lemonde.fr/sciences/article/2021/06/15/des-femmes-atteintes-d-un-cancer-du-sein-metastatique-privees-d-un-traitement-innovant\\_6084174\\_1650684.html](https://www.lemonde.fr/sciences/article/2021/06/15/des-femmes-atteintes-d-un-cancer-du-sein-metastatique-privees-d-un-traitement-innovant_6084174_1650684.html)

<https://www.associationkoeurderose.com/>

<https://fr.thesocialmedwork.com/blog/trodelvy-information>

[https://www.breastcancer.org/treatment/targeted\\_therapies/trodelvy](https://www.breastcancer.org/treatment/targeted_therapies/trodelvy)

<https://www.msn.com/fr-fr/finance/other/des-femmes-atteintes-d-un-cancer-du-sein-d%C3%A9noncent-la-p%C3%A9nurie-du-trodelvy-en-europe/ar-AAKOXGu>

<https://lhchosting.com/covid19/2021/09/08/cancer-du-sein-triple-negatif-le-nouveau-traitement-trodelvy-autorise-en-acces-precoce/>

<https://francais.medscape.com/voirarticle/3607552>

<https://ihaddadene.com/projet/2021/09/07/cancer-du-sein-triple-negatif-le-trodelvy-est-enfin-autorise-en-france/>

<https://eur-lex.europa.eu/legal-content/FR/TXT/?uri=LEGISSUM%3Aasp0002>

<https://pink-ribbon.be/fr/sur-le-cancer-du-sein/cijfers-over-borstkanker-1>

<https://www.monreseau-cancerdusein.com/actualites/les-triplettes-au-magazine-de-la-sante>

[https://drive.google.com/file/d/1RkrrgBrdDERcObsNjPBL6do\\_jB7rhc3B/view](https://drive.google.com/file/d/1RkrrgBrdDERcObsNjPBL6do_jB7rhc3B/view)

---

[1] 10962 cancers du sein détectés en 2019 (10 à 15% : entre 1000 et 1600) <https://www.cancer.be/les-cancers-types-de-cancers-liste-z/cancer-du-sein>

[2] Bardia A et al, Sacituzumab Govitecan in Metastatic Triple-Negative Breast Cancer, *N Engl J Med*, 2021;384:1529-1541. doi: 10.1056/NEJMoa2028485

[3] <https://www.futura-sciences.com/sante/questions-reponses/cancer-immunotherapie-nouveau-traitement-cancer-14408/>