VERSATILE-002

A PDS Biotechnology Trial in HPV-Positive Head and Neck Cancer

Patient Information Booklet

VERSATILE-002 is a global clinical trial combining two medications, PDS0101 and KEYTRUDA® (pembrolizumab), in patients whose head and neck cancer has returned or spread and cannot be removed by surgery.

The head and neck cancer must test positive for HPV16 to be considered for the trial.

PDS Biotechnology

In collaboration with

The Swallows
Head & Neck Cancer Support Group
Registered Charity Number: 1149794

PDS Biotechnology

VERSATILE-002

VERSATILE-002 is a global clinical trial for patients whose head and neck cancer has returned or spread. Patients who enroll in VERSATILE-002 will receive two drugs: PDS0101 and KEYTRUDA®.

KEYTRUDA® is an approved drug for patients whose head and neck cancer has returned or spread. PDS0101 is an investigational medicine targeting human papillomavirus (HPV). PDS0101 has been shown to attack HPV-related cancer.

VERSATILE-002 will study if combining PDS0101 with KEYTRUDA® is more effective than using KEYTRUDA® alone. In this study, all patients who choose to enroll will receive both drugs. There is no placebo.

Many head and neck cancers are caused by HPV infection. Most HPV-related head and neck cancers are caused by HPV16. PDS0101 has been shown to stimulate high levels of HPV16-specific killer T-cells that target and kill head and neck cancers that are caused by HPV infection.

Who is eligible?

You may be able to enroll in the VERSATILE-002 study if you:

- Are an adult who has HPV16 positive head & neck cancer that has come back or spread
- Have recovered from complications from previous major surgeries or radiation therapy
- Are in good overall health (determined by an exam and blood work)

Who is not eligible?

You may be excluded from enrolling in the VERSATILE-002 study if you:

- Are pregnant
- Have active cancer that has spread to the brain
- Have HIV infection
- Developed complications from prior anti-cancer therapy

Interested patients should talk to their doctor to see if they qualify.

What will happen during the study?

If you qualify for and decide to participate in the VERSATILE-002 study:

- You will undergo screening tests
- You will receive KEYTRUDA® treatment every 3 weeks for up to 35 treatments (~2 years)
- PDS0101 will be given in combination with KEYTRUDA® during the first four cycles of treatment and again during cycle 12
- Both medicines are given by injection
- You will have blood work done before each treatment
- You will have imaging studies every 9 weeks for the first year to evaluate the status of your cancer; after the first year, you will be checked every 12 weeks
- You will receive treatment until either the cancer worsens, or you've received 35 treatments (the maximum number given in the study)

Where is the treatment available?

The VERSATILE-002 study is currently being conducted in the following countries:

USA | United Kingdom | Southern Ireland | Spain

The study and hospitals included are currently listed on the US FDA **clinicaltrials.gov** website. Search for '**VERSATILE-002**'

Has your Head and Neck Cancer returned?

If your head and neck cancer has returned or spread and cannot be removed by surgery, you may be eligible for a clinical trial called VERSATILE-002.

Patients who enroll in VERSATILE-002 will receive both KEYTRUDA®, a medication often given to patients with head and neck cancer that has returned or spread, plus a new medication that has been shown to stimulate a strong anti-tumour immune response called PDS0101.

How do I apply?

Ask your current hospital team about the new trial or contact the team using the details on the right.

Place hospital sticker here

Look out for the Head & Neck Cancer warning signs

Early diagnosis can save your life

Persistent sore throat | Foul breath | Hoarseness or voice changes | Swelling of throat | Persistent ear ache or constant pain | Lump, bump or mass without pain | White or red patch | Persistent nasal obstructions or congestions

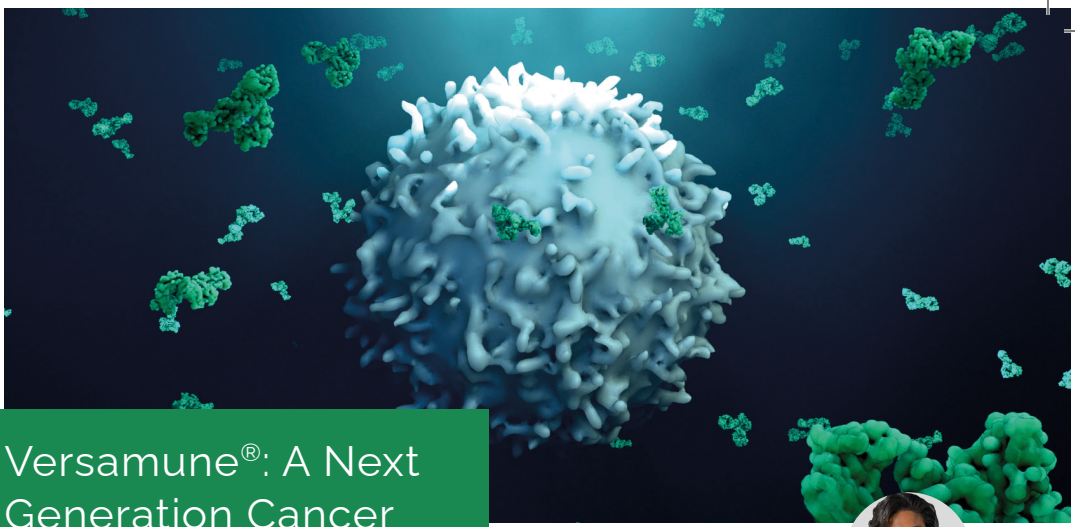
24/7 Patient & Caregiver Support Line

Answered by a patient or caregiver

+44 (0)7504 725 059

Email: **info@theswallows.org.uk** or visit: **theswallows.org.uk**

The Swallows
Head & Neck Cancer Support Group
Registered Charity Number: 1149704



Versamune®: A Next Generation Cancer Immunotherapy

Lauren V. Wood, MD.
Chief Medical Director

The immune system is precise, so it is possible for it to target cancer cells exclusively while sparing healthy cells. Many immunotherapy treatments can also be used in combination with surgery, chemotherapy, radiation, or targeted therapies to improve their effectiveness.

Immunotherapies have recently been recognized as having significant potential to treat a broad range of cancers. Several cancer immunotherapies have now been approved by the FDA, and several other promising immunotherapy technologies and products are in various stages of clinical development.

Versamune®: A Next Generation Cancer Immunotherapy

Despite recent progress in fighting cancer the sad reality is that it remains a leading cause of morbidity and mortality. Some of the most promising new treatments have emerged from the convergence of the oncology and immunology fields. These novel therapies that harness the power of the immune system to fight cancer are called immunotherapies. Indeed, cancer immunotherapies have significant potential to treat a broad range of cancers, and several have been approved by the FDA. To date, however, while progress has been made in developing new anti-cancer immunotherapeutic technologies and products, significant challenges limiting their clinical effectiveness remain.

On a basic immunological level, considerable hurdles impeding the ability of immunotherapy technologies to harness the body's immune system most effectively still persist. For example, approved checkpoint inhibitors have been demonstrated to be effective and, for those patients who respond, the durability of their responses can be significant. Unfortunately, however, the rates of response reported are only in the range of 15-20%. Importantly, immune therapies, including checkpoint inhibitors, CAR-Ts and live-vector vaccines, remain burdened with significant systemic toxicities limiting their use either in early-stage cancer setting or especially in combination with other approved anti-cancer treatments.

Versamune® is a proprietary T-cell activating platform engineered to improve the treatment outcomes of patients with cancer. PDS0101, one of the drugs used in VERSATILE-002, leverages the Versamune® platform to target and attack cancers caused by HPV.

PDS Biotechnology

www.pdsbiotech.com