Vitalis Pharmaceuticals Anticipates Launch of Novel Low-Flush Fumarate by 2021

VTS-72 designed to improve pharmacokinetics and alleviate the Fumarate Flush; highly prevalent side effect of fumarate therapy

NDA submission as early as 2020, followed by potential launch into $4 billion market

VTS-72 has intellectual property protection into 2038 as well as Orphan Drug Designation

NEW YORK, Oct. 22, 2019 (GLOBE NEWSWIRE) -- Vitalis LLC, a privately-held specialty pharmaceutical company leveraging its proprietary VTS-Aspirin platform to overcome the limitations of existing drugs and enhance patient experience across a variety of therapeutic areas, today announced its goal of commercializing its lead product candidate VTS-72 in 2021. VTS-72 is in development for the treatment of patients with relapsing-remitting multiple sclerosis (RRMS) who experience the dimethyl fumarate flush, a common side effect of fumaric acid. It is a proprietary combination of fumarate and VTS-Aspirin, a formulation that improves the pharmacokinetics of fumarate and has shown evidence of reduction of flushing in a pilot clinical study.

Fumaric acid, or fumarates, are the leading orally-administered treatments for RRMS. While fumarates have demonstrated effectiveness at reducing MS flares and slowing disease progression, they can be poorly tolerated. Flush is one of the most commonly-reported adverse events, affecting an estimated 40% of fumarate patients, with a discontinuation rate comparable to that from gastrointestinal side effects. Studies have demonstrated that pre-treating with aspirin 30 minutes before fumarate dosing can significantly reduce flush. However, patient adherence to this regimen is low.

By combining VTS-Aspirin with fumarates, VTS-72 is believed to improve the pharmacokinetics of fumaric acid while alleviating the Fumarate Flush in RRMS patients. An 18-subject pilot study of VTS-72 demonstrated a 63% reduction in flush compared to fumarate monotherapy.

Based on these data, the Company has requested a Type-C meeting with the U.S. Food & Drug Administration (FDA) and, subject to the outcome of this meeting, expects to initiate a pivotal study of VTS-72 in 2020. VTS-72 has been granted Orphan Drug Designation for MS patients who experience the dimethyl fumarate flush. In addition, VTS-72 is expected to utilize the 505(b)(2) regulatory pathway for expedited development with the potential for an NDA submission as early as 2020.

“The Fumarate Flush is not only prevalent but its impact on patient quality of life and compliance with treatment is often significantly underestimated, exacting both a physical and psychological toll on the patient,” said Joseph Habboushe, MD, founder of Vitalis and inventor of the VTS platform. “Flush is also a common side effect of other therapies, such as high-dose niacin, and is known to lead to treatment noncompliance, a high discontinuation rate, and could represent a barrier to initiating patients to fumarate therapy.

Through this propriety combination, we believe that VTS-72 can meaningfully reduce flush while improving the pharmacokinetics of the fumarate, resulting in a potentially significant advancement in the treatment of MS."

Vitalis has several patent families for VTS-72 with the most recent patent issuance by the USPTO extending protection into 2038.

In addition to the continued development of VTS-72, Vitalis is leveraging its VTS-Aspirin platform to develop a non-opioid oral alternative for post-surgical pain after joint replacements, called VTS-K (VTS-Aspirin plus a proprietary formulation of ketamine), aimed at helping shift patients to the outpatient setting.

About Vitalis

Vitalis is a privately-held specialty pharmaceutical company focused on overcoming the limitations of existing drugs using its proprietary VTS-Aspirin platform. Its most advanced product, VTS-72, uniquely combines aspirin with fumaric acid, the leading multiple sclerosis medication, to reduce its most common side effect while improving pharmacokinetics. Similarly, its second candidate, VTS-K, may be the first oral ketamine to enter the market, aiming to reduce opioid need while supplanting injectable blood thinners after joint replacements. For additional information, please visit www.vitalispharma.com.

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