Vitalis Pharmaceuticals Announces Results of Type C Meeting with FDA for VTS-72

Phase 3 Study Expected to Initiate in 2020, with Potential for First New Drug Application in Acute Flush in Multiple Sclerosis (MS) Patients in First Half 2021

Company plans to extend clinical development to other related indications, including MS fatigue, which affects up to 90% of MS patients, and MS exercise intolerance

NEW YORK, Jan. 07, 2020 (GLOBE NEWSWIRE) -- Vitalis LLC, a 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 receipt of the minutes from the U.S. Food and Drug Administration (FDA) following a Type C meeting with the agency. The Type C meeting was held in November 2019 to review a potential path toward a New Drug Application (NDA) for VTS-72, which is in development for the treatment of patients with relapsing-remitting multiple sclerosis (RRMS) who experience the Fumarate Flush, a common side effect of fumaric acid. VTS-72 is a proprietary combination of fumarate and VTS-Aspirin, a formulation that improves the pharmacokinetics of fumarate and demonstrated a 63% reduction of flush in a pilot clinical study.

Based on the outcome of this meeting, Vitalis plans to pursue an initial approval of VTS-72 for the treatment of patients with RRMS who experience the Fumarate Flush. The Company anticipates initiating the necessary dose ranging and bioequivalence studies in the near future, followed by a Phase 3 randomized-controlled trial. The Company believes it could submit an NDA to the FDA for VTS-72 in this indication in the first half of 2021.

Further, Vitalis believes it can pursue development and approval of VTS-72 in other related indications, including chronic flush reduction, MS-related fatigue and MS-related exercise intolerance. The Company is also exploring the possibility that its unique aspirin and fumarate combination may be studied head-to-head versus currently approved fumarate treatments, to test for superiority in MS flare reduction itself. If such an approach were successful, it could position VTS-72 as a best-in-class fumarate and help establish it as a new standard of care for the treatment of RRMS.

“We had a very productive engagement with the FDA to determine the path forward for the development of VTS-72 in RRMS patients who experience Fumarate Flush,” said Joseph Habboushe, MD MBA, founder of Vitalis and inventor of the VTS platform. “Based on the feedback we received from the FDA, we expect to initiate a single pivotal trial this year and to submit an NDA in 2021 for our initial indication of acute flush reduction. This timeline aligns with a potential commercial launch of VTS-72 in this indication, if approved, in late 2021. Based on existing literature supporting the use of aspirin in MS, Vitalis aims to seek additional subsequent approvals in other MS-related indications. We are excited by what the future holds for VTS-72 as we have multiple opportunities to capitalize on the significant

potential in the MS space and are supported by both a robust IP estate and freedom to operate in this rapidly evolving market."

Victoria M. Leavitt, Ph.D., Assistant Professor of Neuropsychology at Columbia University Medical Center, added, "Aspirin has been a major focus of my laboratory's research because of its surprisingly underrecognized potential to improve the lives of people with MS on multiple levels. In addition to published evidence showing it reduces fatigue in MS patients, the research we are currently conducting in my lab reveals a beneficial effect of aspirin pre-treatment for improving exercise performance. Reducing barriers to exercise is critical for everyone, particularly for people with MS who are uniquely susceptible to overheating, one likely common culprit for both MS-related fatigue and MS exercise intolerance."

Dr. Leavitt commented that her approach required pre-treatment of one hour with aspirin, which could possibly be replaced with the use of VTS-72.

It is thought that MS overheating, classically known as Uhthoff's phenomena, may be the common cause of both MS fatigue, also known as *lassitude*, and MS exercise intolerance. It has been reported that lassitude affects up to 90% of MS patients. There are currently no FDA approved treatments for lassitude or MS exercise intolerance.

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 the most commonly reported adverse event, 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.

VTS-72 has been granted Orphan Drug Designation for MS patients who experience the Fumarate Flush. In addition, VTS-72 is expected to utilize the 505(b)(2) regulatory pathway for expedited development.

Biogen's Tecfidera® currently leads the market with $4.4 billion in annualized sales. Recently Biogen has had a second drug approved, Vumerity™, in the fumarate MS space.

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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