***Source:*** *Vitalis Pharmaceuticals*

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# Vitalis Receives Orphan Drug Designation for Diroximel Fumarate and Monomethyl Fumarate, in Combination with VTS-Aspirin, for Multiple Sclerosis Patients Who Experience Fumarate Flush

NEW YORK, April 21, 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 that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for diroximel fumarate (commercially available as Vumerity®) and monomethyl fumarate (FDA approved as Bafiertam™), both in combination with VTS-Aspirin, for the treatment of relapsing/remitting multiple sclerosis (RRMS) patients who experience fumarate flush. The Company previously received orphan drug designation for its lead clinical candidate, VTS-72, a proprietary combination of dimethyl fumarate (commercially available as Tecfidera®) and aspirin for the treatment of RRMS patients who experience fumarate flush.

“Fumarates, an important class of oral drugs to treat RRMS, cause fumarate flush in as many as 40% of patients,” said Joseph Habboushe, M.D., MBA., founder of Vitalis and inventor of the VTS platform. “This is a significant side effect and can lead to skipping of doses or, in some cases, treatment discontinuation. VTS-72 significantly reduced fumarate flush in an 18-patient pilot study, and we expect to initiate a pivotal trial later this year. Diroximel fumarate and monomethyl fumarate are two different fumarate salts that are used today for treating RRMS patients but, like dimethyl fumarate, can cause fumarate flush. Because of the potential clinical benefit of combining these fumarates with aspirin, we were able to obtain Orphan Drug Status for each, in combination with VTS-Aspirin, to treat patients that experience fumarate flush. We believe that combining fumarates with VTS-Aspirin can bring meaningful tolerability benefits to RRMS patients and we will continue to evaluate the potential of these combinations. We believe that FDA’s recognition of this subset of patients as an orphan population speaks to the unmet need for an effective method of treating fumarate flush, as our product candidates are the first adult MS therapies to receive orphan designation in over 15 years.”

The FDA’s Office of Orphan Products Development (OOPD) grants orphan designation status to a drug that is intended to treat a rare disease or condition that affects fewer than 200,000 persons in the United States. Orphan drug designation provides certain benefits and incentives that may include tax credits towards the cost of clinical trials and prescription drug user fee waivers and the potential for seven years of market exclusivity in the United States upon regulatory approval.

**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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