Strongbridge Biopharma plc Announces Acquisition of U.S. Rights to KEVEYIS® From Taro

December 23, 2016 8:01 AM ET

~ KEVEYIS is the First and Only FDA-Approved Treatment for Hyperkalemic, Hypokalemic, and Related Variants of Primary Periodic Paralysis, an Ultra-Orphan, Genetic Neuromuscular Disease ~

~ KEVEYIS is Strongbridge's First Commercial Product and Expands its Rare Disease Portfolio ~

DUBLIN, Ireland and TREVOSE, Pa., Dec. 23, 2016 (GLOBE NEWSWIRE) -- Strongbridge Biopharma plc, (Nasdaq:SBBP), a global commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs, today announced that the Company has acquired the U.S. rights to KEVEYIS® (dichlorphenamide) from a subsidiary of Taro Pharmaceutical Industries Ltd. ("Taro"). KEVEYIS was approved by the U.S. Food and Drug Administration (FDA) in August 2015 to treat hyperkalemic, hypokalemic, and related variants of Primary Periodic Paralysis, which is a group of rare hereditary disorders that causes potentially severe episodes of muscle weakness and/or paralysis. KEVEYIS has orphan drug exclusivity status in the U.S. through August 7, 2022.

"The acquisition of KEVEYIS is transformational for Strongbridge and expands our rare disease portfolio to include neuromuscular diseases," said Matthew Pauls, president and chief executive officer of Strongbridge. "We look forward to working closely with the Primary Periodic Paralysis community to help make a meaningful difference in the lives of those affected by this rare and underserved disease," Pauls added.

Under the terms of the purchase agreement, Strongbridge will provide Taro with upfront and deferred payments of $8.5 million in two installments; Taro is also eligible to receive additional future payments upon the achievement of certain sales unit milestones. Strongbridge expects to commercially launch KEVEYIS in the U.S. in April 2017. Taro has agreed to continue to manufacture KEVEYIS for Strongbridge under an exclusive supply agreement at least for the period of KEVEYIS orphan exclusivity, subject to certain commercial terms and conditions, including minimum supply purchases.

Since May 2016, Taro has been supplying KEVEYIS to patients through a compassionate use program. Strongbridge will continue this program through at least April 1, 2017. Strongbridge is committed to working with existing U.S. KEVEYIS patients to ensure continuity of treatment. KEVEYIS patients may call 1-844-KEVEYIS for more information.

Locust Walk served as Strongbridge's transaction advisor.

About Strongbridge Biopharma
Strongbridge Biopharma is a global commercial-stage biopharmaceutical company focused on the development and commercialization of therapies for rare diseases with significant unmet needs. Strongbridge's first commercial product is KEVEYIS® (dichlorphenamide), the first and only FDA-approved treatment for hyperkalemic, hypokalemic, and related variants of Primary Periodic Paralysis. KEVEYIS has orphan drug exclusivity status in the U.S. through August 7, 2022. In addition to establishing this neuromuscular disease franchise, the Company has a clinical-stage pipeline of therapies for rare endocrine diseases. Strongbridge's lead compounds include COR-003 (levoketoconazole), a cortisol synthesis inhibitor currently being studied for the treatment of endogenous Cushing's syndrome, and COR-005, a next-generation somatostatin analog (SSA) being investigated for the treatment of acromegaly, with potential additional applications in Cushing's syndrome and neuroendocrine tumors. Both COR-003 and COR-005 have received orphan designation from the U.S. Food and Drug Administration and the European Medicines Agency. For more information, visit www.strongbridgebio.com.

ABOUT KEVEYIS

KEVEYIS® Indication

KEVEYIS® (dichlorphenamide) is indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.

KEVEYIS Important Safety Information
In clinical studies, the most common side effects of KEVEYIS were a numbness or tingling, difficulty thinking and paying attention, changes in taste, and confusion. These are not all of the possible side effects that you may experience with KEVEYIS. Talk to your doctor if you have any symptoms that bother you or do not go away.

KEVEYIS is not for everyone. Do not take KEVEYIS if you:

- Are on a high-dose aspirin regimen
- Are allergic to sulfa-based drugs
- Have liver, kidney, or certain lung conditions
- Are pregnant, planning to become pregnant, or nursing
- Are under 18 years old

Taking KEVEYIS may cause a drop in the amount of potassium (an electrolyte) in your body, which can lead to heart problems. Ask your doctor if you need to eat foods that contain high amounts of potassium while taking KEVEYIS.

Your body may produce too much acid or may not be able to remove enough acid from body fluids while taking KEVEYIS. Your doctor will run tests on a regular basis to check for signs of acid buildup and may reduce your dose or stop your treatment with KEVEYIS.

KEVEYIS may also increase the risk of falls, especially in elderly patients and patients taking high doses of KEVEYIS. Use caution when driving, operating machinery, or performing any other hazardous activities while taking KEVEYIS, as this medication may cause drowsiness.

You are encouraged to report side effects to Strongbridge Biopharma at 1-855-324-8912, or to the FDA at 1-800-FDA-1088 or visit **www.fda.gov/medwatch/**. For more information, go to **www.keveyis.com**.

For additional KEVEYIS important safety information, please see full prescribing information at **www.keveyis.com**.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, are forward-looking statements. These statements relate to future events and involve known and unknown risks, including, without limitation, uncertainties regarding Strongbridge's strategy, plans, anticipated investments, costs and results and objectives of management for future operations. The words "anticipate," "estimate," "expect," "intend," "may," "plan," "potential," "project," "target," "will," "would," or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are based on current expectations, estimates, forecasts and projections and are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors. The forward-looking statements contained in this press release are made as of the date of this press release, and Strongbridge Biopharma does not assume any obligation to update any forward-looking statements except as required by applicable law.

Contacts:

Corporate and Media Relations
Elixir Health Public Relations

Lindsay Rocco
+1 862-596-1304
lrocco@elixirhealthpr.com

Investor Relations
The Trout Group
Marcy Nanus
+1 646-378-2927
mnanus@troutgroup.com

USA
900 Northbrook Drive
Suite 200
Trevose, PA 19053
Tel. +1 610-254-9200
Fax. +1 215-355-7389

Strongbridge Biopharma plc