Sorrento Therapeutics Logo

FDA Acknowledges Receipt Of Sorrento Therapeutics Inc, NDA For ZTlido™; PDUFA Date Set For February 28, 2018

September 12, 2017

SAN DIEGO, Sept. 12, 2017 /PRNewswire/ -- Sorrento Therapeutics, Inc. (NASDAQ: SRNE, "Sorrento"), announced today that SCILEX Pharmaceuticals Inc. ("SCILEX"), a majority-owned subsidiary of Sorrento, has received from the U.S. Food and Drug Administration ("FDA") acknowledgement of receipt of its recently resubmitted New Drug Application ("NDA") for ZTlido™ (lidocaine patch 1.8%) which has been considered a complete, class 2 response to the prior action letter.

The PDUFA (Prescription Drug User Fee Act) goal date for completion of the FDA's review of the SCILEX NDA is set for February 28, 2018, which is the standard six-month review period for a class 2 response.

About SCILEX Pharmaceuticals Inc.

SCILEX, a majority-owned subsidiary of Sorrento Therapeutics located in San Diego, California, leverages on its core, proprietary technologies to responsibly develop next generation, branded pharmaceutical products to better manage critical conditions and maximize the quality of life of patients and healthcare providers. We are uncompromising in our focus to become the global pharmaceutical leader committed to social, environmental, economic, and ethical responsibility. Leveraging on our global partnerships, we deliver the next generation of trailblazing products that are responsible by design. The Company's lead product under development, ZTlido™ (lidocaine patch 1.8%), is a branded lidocaine patch formulation for the treatment of relieving the pain of post-herpetic neuralgia, also referred to as after-shingles pain. For more information visit www.scilexpharma.com.

About Sorrento Therapeutics, Inc.

Sorrento is a clinical stage, antibody-centric, biopharmaceutical company developing new therapies to turn malignant cancers into manageable and possibly curable diseases. Sorrento's multimodal multipronged approach to fighting cancer is made possible by its' extensive immuno-oncology platforms, including key assets such as fully human antibodies ("G-MAB™ library"), clinical stage immuno-cellular therapies ("CAR-T"), intracellular targeting antibodies ("iTAbs"), antibody-drug conjugates ("ADC"), and clinical stage oncolytic virus ("Sephrevir®").

Sorrento's commitment to life-enhancing therapies for cancer patients is also demonstrated by our effort to advance a first-in-class (TRPV1 agonist) non-opioid pain management small molecule in Resiniferatoxin ("RTX") and ZTlido. Resiniferatoxin is completing a phase IB trial in terminal cancer patients. ZTlido is in regulatory review following NDA re-submission.

For more information visit www.sorrentotherapeutics.com

Forward-Looking Statements

This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Sorrento Therapeutics, Inc. and its subsidiaries under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements regarding the timing of the review of the NDA for ZTlido, Scilex's prospects, Sorrento's strategy and other forward-looking statements. Risks and uncertainties that could cause our actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: that the review of the NDA may not proceed in a timely manner and other risks that are described in Sorrento's most recent periodic reports filed with the Securities and Exchange Commission, including Sorrento's Annual Report on Form 10-K for the year ended December 31, 2016, as amended. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release and we undertake no obligation to update any forward-looking statement in this press release except as required by law.

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