

December 5, 2018

# Phase 3 Trial of Rova-T as Second-line Therapy for Advanced Small-Cell Lung Cancer (TAHOE Study) Halted



**- Independent Data Monitoring Committee responsible for ongoing review of study data recommended enrollment be stopped**

NORTH CHICAGO, Ill., Dec. 5, 2018 /PRNewswire/ -- AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, today announced the decision to stop enrollment for the TAHOE trial, a Phase 3 study evaluating Rovalpituzumab Tesirine (Rova-T) as a second-line therapy for advanced small-cell lung cancer (SCLC). An Independent Data Monitoring Committee (IDMC) recommended stopping enrollment in TAHOE due to shorter overall survival in the Rova-T arm compared with the topotecan control arm. For patients currently on treatment with Rova-T in TAHOE, the IDMC recommended that investigators and patients make individual decisions as to whether or not to continue treatment based on patient level response. The recommendation from the IDMC to halt enrollment applies only to the TAHOE study and does not impact other Rova-T clinical studies.

"Patients are our first priority and we are deeply grateful to the patients and physicians who participated in this trial," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. "We remain committed to discovering and developing transformative therapies for people living with cancer."

## About the TAHOE Trial

The TAHOE trial is a randomized, open-label, two-arm, Phase 3 trial assessing the efficacy, safety and tolerability of Rova-T versus topotecan in participants with advanced or metastatic small-cell lung cancer (SCLC) with high levels of delta-like protein 3 (DLL3) and who have first disease progression during or following front-line platinum-based chemotherapy.

## About Rovalpituzumab Tesirine (Rova-T)

Rova-T is an investigational antibody-drug conjugate targeting the cancer-stem cell-associated delta-like protein 3 (DLL3)<sup>1</sup>, which is expressed in more than 80 percent of small-cell lung cancer (SCLC) patient tumors, where it is prevalent on tumor cells, including cancer stem cells, but not present in healthy tissue.<sup>2</sup> Rova-T combines a targeted antibody that delivers a cytotoxic agent directly to the DLL3-expressing cancer cells while minimizing toxicity to healthy cells. Rova-T is under investigation as a third-line treatment in SCLC.<sup>2</sup> The expression of DLL3 suggests Rova-T may be useful across multiple tumor types, including metastatic melanoma, glioblastoma multiforme and some prostate, pancreatic and colorectal cancers.<sup>2</sup>

Rova-T is an investigational compound and its efficacy and safety have not been established by the FDA or any other health authority.

## About AbbVie in Oncology

At AbbVie, we strive to discover and develop medicines that deliver transformational improvements in cancer treatment by uniquely combining our deep knowledge in core areas of biology with cutting-edge technologies, and by working together with our partners – scientists, clinical experts, industry peers, advocates, and patients. We remain focused on delivering these transformative advances in treatment across some of the most debilitating and widespread cancers. We are also committed to exploring solutions to help patients obtain access to our cancer medicines. With the acquisitions of Pharmacyclics in 2015 and Stemcentrx in 2016, our research and development efforts, and through collaborations, AbbVie's oncology portfolio now consists of marketed medicines and a pipeline containing multiple new molecules being evaluated worldwide in more than 200 clinical trials and more than 20 different tumor types. For more information, please visit <http://www.abbvie.com/oncology>.

## About AbbVie

AbbVie is a global, research and development-based biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at [www.abbvie.com](http://www.abbvie.com). Follow [@abbvie](#) on Twitter, [Facebook](#), [LinkedIn](#) or [Instagram](#).

## Forward-Looking Statements

Some statements in this news release are, or may be considered, forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2017 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

<sup>1</sup> Saunders L. R. et al. A DLL3-targeted antibody-drug conjugate eradicates high-grade pulmonary neuroendocrine tumor-initiating cells in vivo. *Sci. Transl. Med.* 2015;7(302): 1-13.

<sup>2</sup> ClinicalTrials.gov (2016). Study of Rovalpituzumab Tesirine (SC16LD6.5) for Third-line and Later Treatment of Subjects With Relapsed or Refractory Delta-Like Protein 3-Expressing Small Cell Lung Cancer (TRINITY). Accessed March 21, 2018. <https://clinicaltrials.gov/ct2/show/NCT02674568?term=SC16LD6.5&rank=2>.

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## Contact(s)

### Media

Jackie Finley  
+1 (847) 937-3998  
jaquelin.finley@abbvie.com  
OR

### Investors






Liz Shea  
+1 (847) 935-2211  
liz.shea@abbvie.com

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