

Antibe Therapeutics, Inc.

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Antibe Therapeutics updates on Phase 2 progress of lead drug ATB-346

Antibe Therapeutics Inc (CVE:ATE) (OTCMKTS:ATBPF) released a shareholder update Tuesday, including highlights about the company's Phase 2 development for its flagship ATB-346 drug, as the firm launches into global partnering discussions.

Antibe's lead drug, ATB-346, targets acute and chronic pain associated with osteoarthritis and its Phase 2B dose-ranging, efficacy study for the drug remains on track.

It's been a pivotal year for the company, which launched its head-to-head Phase 2B study versus naproxen, the most prescribed NSAID in the United States.

READ: Antibe Therapeutics CEO Dan Legault on why the multibillion-dollar NSAID market needs disruption

"Our overarching objective for shareholders remains the same: monetize our drug pipeline through high-value partnerships for the large pharmaceutical markets," said CEO Dan Legault in a statement. "Given the strength of our existing data package and the successful conclusion of Phase 2 within our reach, we feel we are well positioned to deliver upon that goal."

The company's Phase 2B efficacy study has a total of 360 patients across 35 clinical sites, in "one of the largest clinical studies ever undertaken in Canada," noted the firm. The company says a successful trial will validate the best-in-class status of the drug in a US\$11 billion drug category and could set the stage for global partnering activity.

The study is designed to validate the effectiveness of ATB-346 in reducing osteoarthritis pain and establish the lowest effective dose.

"Importantly, this is the final Phase 2 study for ATB-346 and represents a major development milestone and inflection point for Antibe if one of the doses meets the primary endpoint," said Legault.

Gearing up for FDA meeting

Antibe is also working on getting the drug ready for an investigational new drug (IND) application, as well as a end-of-Phase-2 meeting with the FDA. The preparation is intense, requiring comprehensive data packages encompassing pharmacokinetics, metabolism, toxicology, chemistry and manufacturing, among other factors.

The company has assembled a team of regulatory experts to support the initiative, including several former heads of FDA directorates and a regulatory agency based out of Washington, DC.

READ: Antibe Therapeutics is poised to disrupt the global pain management industry

The company also noted it has seen mounting interest in ATB-346 and is in discussions with a number of pharmaceutical companies.

Price: 0.425

Market Cap: \$116.52 m

1 Year Share Price Graph



Share Information

Code: ATE

Listing: TSX-V

52 week High Low
0.54 0.235

Sector: Pharma & Biotech

Website: antibethera.com

Company Synopsis:

Antibe Therapeutics is a publicly-traded biotechnology company pursuing a breakthrough advance in the treatment and prevention of inflammation. Antibe's drug pipeline addresses a \$20+ billion market in non-addictive pain management, cardiovascular disease, and cancer prevention.

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"Assuming the Phase 2B efficacy results are favourable, we anticipate being in a position of strength to execute a series of regional and global licensing deals," said Legault.

Also pushing forward its non-opioid acute painkiller

In addition to its lead drug, ATB-346, the firm also continues to leverage its hydrogen sulfide (H2S) technology platform and work on the next drug in its pipeline, ATB-352, a non-addictive, potent analgesic for treating acute pain. ATB 352 is a derivative of ketoprofen, a potent NSAID for acute pain. Its intended use will be in competition with strong opioids such as fentanyl and oxycontin.

"Post-operative pain is a US\$9 billion market opportunity that is in desperate need of safer treatment alternatives without abuse potential," said Legault. "Furthermore, the recent characterization of our strategy for ATB-352 affirms to potential partners that Antibe is building a best-in-class platform of drug candidates that address several blockbuster markets."

Regenerative medicine asset delivering impressive growth

The company also noted Citagenix Inc., its commercial asset in regenerative medicine, is seeing strong growth as it continues its US expansion.

Sales in the United States were up 62% year-over-year in fiscal 2019 and the company says it is seeing the growth rate accelerate currently.

"We expect its recent performance to benefit strategic discussions that are geared to unlock additional value for shareholders," said Legault.

Shares of Antibe Therapeutics were up 3.1% at C\$0.33 in Toronto, up 5% at US\$0.25 in New York on Tuesday.

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