Press Release

Abliva AB (publ), 556595-6538
31 May 2022 20:45:00 CEST - Lund, Sweden

NOT FOR RELEASE, DISTRIBUTION OR PUBLICATION, DIRECTLY OR INDIRECTLY, IN OR INTO AUSTRALIA, CANADA, HONG KONG, JAPAN, NEW ZEALAND, SINGAPORE, SOUTH AFRICA, SWITZERLAND, RUSSIA, BELARUS, THE UNITED STATES OR ANY OTHER JURISDICTION, WHERE SUCH ACTIONS ARE SUBJECT TO LEGAL RESTRICTIONS. THIS PRESS RELEASE DOES NOT CONSTITUTE AN OFFER REGARDING ANY SECURITIES IN ABLIVA.

Abliva targets SEK 200 million raise to fund the KL1333 Phase 2/3 study to interim analysis

Abliva AB (Nasdaq Stockholm: ABLI) today announced that it intends to raise a financing round of SEK 200 million to provide the company with the capital necessary to run the Phase 2/3 study with KL1333 to a key interim analysis, progress NV354 to be clinic-ready, and provide the company with 24 months of cash runway. The financing round will be comprised of a SEK 150 million directed issue, including participation by new specialist investor IP Group and existing venture capital investor, Hadean Ventures, as well as a fully underwritten SEK 50 million rights issue. The subscription price will be the same in both the directed issue and the rights issue, with an ambition to have a discount of no more than 10 percent compared to closing price per today, May 31, 2022. Abliva's largest shareholder, Hadean Ventures, intend to convert all their convertibles, at an aggregated nominal value of SEK 26 million, together with accrued interest, to shares in connection to the financing round.

The majority of the proceeds from the SEK 200 million raise will be used to initiate a registrational, Phase 2/3 clinical trial evaluating KL1333 for the treatment of adults suffering from primary mitochondrial disease. This global study is expected to start screening patients in the second half of 2022. The financing procured will support recruitment of the first 40 patients in the study and progression of these patients to a key interim analysis in late 2023 /early 2024. The interim analysis will provide important safety and efficacy information (through a conditional power analysis) followed by progression into the second stage of the seamless platform design, with either continuation at the planned study size or expansion up to a pre-defined cap. The interim analysis will also include a standard futility analysis. The full study readout from the Phase 2/3 study is anticipated in early 2026. The robust nature of the interim analysis, which, as noted, will provide important information in late 2023/early 2024, has been well received by investors and potential strategic partners as providing an early inflection point for Abliva’s lead programme.

The rest of the proceeds will be used to progress NV354 to be ready for the clinic as well as support the company. In particular, the proceeds will fund the manufacturing of clinical trial material and submission of the appropriate regulatory documentation to support a Phase 1 start for NV354. The company will continue to be run in lean manner with limited overhead and fiscal conservatism. The financing will provide the company with twenty-four months of runway through mid-2024.

Abliva AB (publ) - the mitochondrial medicine company. The company is listed on Nasdaq Stockholm, Small Cap, under the ticker symbol ABLI.

Commenting on the intended financing, Ellen Donnelly, CEO, commented: "We are delighted that this intended raise will support progressing our lead asset into a Phase 2/3 registrational study bringing it one step closer to helping patients all over the world with this serious disease. Over the next months we will finalize the study design with regulators and look forward to screening the first patients in the second half of this year. We can now look forward with confidence to a major inflection point as we get our interim data, planned for late 2023/early 2024."

This information is information that Abliva AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out below, at 2022-05-31 20:45 CEST.

For more information, please contact:

Catharina Johansson, Deputy CEO, CFO & VP Investor Relations
+46 (0)46-275 62 21, ir@abliva.com

Abliva AB (publ)
Medicon Village, SE-223 81 Lund, Sweden
Tel: +46 (0)46 275 62 20 (switchboard)
info@abliva.com, www.abliva.com

Subscribe to our news: https://abliva.com/posts/news-subscription/
Follow us on LinkedIn: https://www.linkedin.com/company/abliva
Subscribe to our YouTube channel: https://www.youtube.com/channel/UChqP7Ky5caXtp72CELhD6Mg

Abliva – Delivering mitochondrial health

Abliva discovers and develops medicines for the treatment of primary mitochondrial diseases. These rare and often very severe diseases occur when the cell's energy provider, the mitochondria, do not function properly. The company has prioritized two projects. KL1333, a powerful regulator of the essential co-enzymes NAD^+ and NADH, is entering late-stage development. NV354, an energy replacement therapy, has completed preclinical development. Abliva, based in Lund, Sweden, is listed on Nasdaq Stockholm, Sweden (ticker: ABLI).

Press Release

Abliva AB (publ), 556595-6538
31 May 2022 20:45:00 CEST - Lund, Sweden

Important information

Release, announcement or distribution of this press release may, in certain jurisdictions, be subject to restrictions according to law and persons in those jurisdictions, in which this press release has been announced or distributed, should inform themselves of and follow such legal restrictions. This press release does not constitute an offer, or a solicitation of any offer, to buy or subscribe for any securities in Abliva in any jurisdiction.

This press release does not constitute or form part of an offer or solicitation to purchase or subscribe for securities in the United States. The securities referred to herein may not be sold in the United States absent registration or an exemption from registration under the US Securities Act of 1933, as amended. The information in this press release may not be announced, published or distributed to Australia, Canada, Hong Kong, Japan, New Zealand, Singapore, South Africa, Switzerland, Russia, Belarus, the United States or in any other jurisdiction where the announcement, publication or distribution of the information would not comply with applicable laws and regulations.

This press release is not a prospectus. Abliva has not authorized any offer to the public of shares or rights in any member state of the EEA and no prospectus has been prepared or will be prepared in connection with the Directed issue.

Attachments

Abliva targets SEK 200 million raise to fund the KL1333 Phase 2/3 study to interim analysis