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Can-Fite announces positive ph III psoriasis interim data analysis

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Can-Fite BioPharma Ltd., a biotechnology company based out in Israel, advancing a pipeline of proprietary small molecule drugs that address inflammatory, cancer and liver diseases, has announced that the Independent Data Monitoring Committee (IDMC) which conducted an interim analysis of the company's phase III Comfort™ trial of Piclidenoson in the treatment of moderate-to-severe plaque psoriasis, recommended, based on the positive data, to continue the study with the original sample size and drop one dose group. This means that an optimal dose has been found and that the study can be concluded earlier than has been originally planned.

The company plans to undertake a detailed analysis of the data of the RA study and decide on the next steps. Can-Fite's Comfort™ phase III psoriasis study is designed to establish Piclidenoson's superiority compared to placebo and non-inferiority compared to Apremilast (Otezla®) in patients with moderate to severe plaque psoriasis.

The randomized, double-blind study is being conducted in Europe, Israel, and Canada. Patients were randomized into four groups: 2 mg Piclidenoson, 3 mg Piclidenoson, Otezla®, and placebo. The study's primary endpoint is the proportion of patients who achieve a PASI score response of ?75% (PASI 75) vs. placebo at week 16.

The majority of costs associated with the phase III Comfort™ study were previously paid, and based on the company's current cash and its anticipated uses, the Company believes it has sufficient runway to cover the completion of this study.

Piclidenoson has been out-licensed for the indication of psoriasis in Canada, South Korea, Spain, Austria, Switzerland, Hong Kong, Macau, Taiwan, and China. According to iHealthcareAnalyst, the psoriasis therapeutics market is estimated to reach $11.3 billion by 2025.