



Eupraxia Pharmaceuticals Announces Data from RESOLVE Phase 1b/2a Trial of EP-104GI for Treatment of Eosinophilic Esophagitis

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- Consistent improvement in patient reported outcomes with 10 of 11 evaluable patients in the first four cohorts experiencing a reduction in symptom (SDI¹) scores at 12 weeks
- The fourth cohort showed the greatest percentage change in histology (EoEHSS²) scores of any cohort to date
- The RESOLVE Phase 1b/2a trial is progressing as anticipated with no serious adverse events reported in all four fully-dosed cohorts

VICTORIA, BC, Sept. 11, 2024 /CNW/ - Eupraxia Pharmaceuticals Inc. ("Eupraxia" or the "Company") (TSX: EPRX) (NASDAQ: EPRX), a clinical-stage biotechnology company leveraging its proprietary DiffuSphere™ technology to optimize drug delivery for applications with significant unmet need, today announced additional positive clinical data from its RESOLVE Phase 1b/2a trial, which is evaluating the safety and efficacy of EP-104GI as a treatment for eosinophilic esophagitis ("EoE").



New Clinical Data from the Fourth Cohort of the RESOLVE Trial

The results announced today from the fourth cohort of the RESOLVE trial, using Eupraxia's DiffuSphere™ technology for EoE, are derived from twelve 2.5 mg injections of EP-104GI (total dose of 30 mg) administered to less than two-thirds of each patient's lower esophagus. The data show:

- Straumann Dysphagia Index ("SDI")¹, a patient-reported outcome measure designed to assess symptom severity, was lower for all three patients post-administration with peak reductions up to four points (67% from baseline). At 12 weeks post-administration, SDI was reduced by a mean of 45% or 3.3 points – a level comparable with currently approved therapies.
- Eosinophilic Esophagitis Histology Scoring System ("EoEHSS")² scores, which evaluate the severity and extent of EoE, showed the largest percent reduction of any cohort to date, with a mean 39% reduction in Composite Stage and a mean 37% reduction in Composite Grade at 12 weeks – a level comparable with currently approved therapies.
- Using data from four biopsy sites, which is consistent with the U.S. Food and Drug Administration ("FDA") Guidance for Developing Drugs for the Treatment of EoE, the mean reduction in Peak Eosinophil Counts ("PEC")³ was 67% at 12 weeks.

Notes

1. Straumann Dysphagia Index, or SDI, is a patient-reported outcome score that uses a seven-day recall measuring dysphagia (trouble swallowing) severity and frequency. A reduction in SDI is a positive outcome for the RESOLVE trial.
2. In the Eosinophilic Esophagitis Histology Scoring System, or EoEHSS, grade indicates the severity of each of the eight histologic features assessed by the EoEHSS while stage indicates their extent. For the RESOLVE trial, these features include inflammation, increased cell production in a normal tissue or organ, and fibrosis, also known as fibrotic scarring, and five other features. A reduction in EoEHSS is a positive outcome for the RESOLVE trial.
3. Peak Eosinophil Counts, or PEC, means the peak number of eosinophils found in esophageal biopsies. Eosinophils are one of several white blood cells that support a person's immune system. A reduction in PEC is a positive outcome for the RESOLVE trial.

"The RESOLVE trial is progressing rapidly and we continue to observe positive data on efficacy and safety outcomes with EP-104GI, with the fifth cohort expected to read out in November 2024," said Dr. James Helliwell, Chief Executive Officer of Eupraxia. "Overall, we are encouraged by the data that we have seen across a number of key metrics and remain optimistic that we'll see further improvements in patient response as the trial progresses towards an optimal dosing level."

The RESOLVE trial is a Phase 1b/2a, multicentre, open-label, dose-escalation study to evaluate the safety, tolerability,

pharmacokinetics, and efficacy of EP-104GI in adults with histologically confirmed, active EoE. EP-104GI is administered as a single dose via 4 to 20 injections into the esophageal wall. Dose escalations increase the dose per site and/or number of sites. Participants in the first through the fourth cohorts will be assessed for up to 24 weeks. Patients in cohorts five and above will be assessed for 52 weeks.

Dr. Helliwell added, "In each of the trial's successive cohorts, patients are injected with EP-104GI at either higher doses or across a greater number of injection sites. We anticipate that the dose-escalating cohorts will allow us to evaluate the trial's emerging dose-response relationship. In addition, biopsies measuring tissue health have demonstrated a correlation between the dose of drug and the response on histology. This is exactly the outcome we hope to see in a dose-escalation trial such as this."

Dr. Evan S. Dellon, MD, MPH (University of North Carolina School of Medicine) and Chairman of the Company's Gastrointestinal Clinical Advisory Board, commented, "I'm encouraged to see the positive trends in the SDI¹, EoEHSS² and PEC³ scores as the trial continues. These metrics have emerged as key data points to help clinicians better understand a patient's esophageal health and will be important in informing the design of the Company's late-stage clinical trials. We believe that EP-104GI has the potential to contribute to improved overall esophageal health in patients, in part, because it is being injected into the deeper areas of the esophagus versus coating the surface of the tissues, which may help to improve esophageal remodeling."

The Company intends to continue to periodically disclose additional data from the trial.

New Clinical Data from the Third Cohort in the RESOLVE Trial

The results announced today from the third cohort of the RESOLVE trial, using Eupraxia's DiffuSphere™ technology for EoE, are derived from eight 2.5mg injections of EP-104GI (total dose of 20 mg) administered to a portion of each patient's lower esophagus. The data show:

- SDI¹ was 50% lower in one of two evaluable patients at 24 weeks. A third patient in this cohort discontinued evaluation for reasons unrelated to the study.
- EoEHSS² Composite Stage and Composite Grade scores were both lower than baseline at 12 weeks post-administration, showing an average reduction of 7% and 15%, respectively.
- Using data from four biopsy sites, which is consistent with the FDA Guidance for Developing Drugs for the Treatment of EoE, the mean reduction in PEC³ was 55% at 12 weeks.

About EoE

EoE is an inflammatory-mediated disease in which white blood cells migrate into and become trapped in the esophagus, creating pain and difficulty with swallowing food. According to market research from Clearview, EoE affects more than 450,000 people in the United States and has been identified by the American Gastroenterological Association as rapidly increasing in both incidence and prevalence. Impacts from both symptoms and interventions frequently lead to mental health issues, compounding the disease burden of EoE for both the healthcare system and the individual.

About Eupraxia Pharmaceuticals Inc.


Eupraxia is a clinical-stage biotechnology company focused on the development of locally delivered, extended-release products that have the potential to address therapeutic areas with high unmet medical need. DiffuSphere™, a proprietary, polymer-based micro-sphere technology, is designed to facilitate targeted drug delivery of both existing and novel drugs. The technology is designed to support extended duration of effect and delivery of drugs in a hyper-localized fashion, targeting only the tissues that physicians are wanting to treat. We believe the potential for fewer adverse events may be achieved through the precision targeting and the stable and flat delivery of the active ingredient when using the DiffuSphere™ technology, versus the peaks and troughs seen with more traditional drug delivery methods. The precision of Eupraxia's DiffuSphere™ technology platform has the potential to augment and transform existing FDA-approved drugs to improve their safety, tolerability, efficacy and duration of effect. The potential uses in therapeutic areas may go beyond pain and inflammatory gastrointestinal disease, where Eupraxia currently is developing advanced treatments, to also be applicable in oncology, infectious disease and other critical disease areas.

Eupraxia's EP-104GI is currently in a Phase 1b/2a trial, the RESOLVE trial, for the treatment of EoE. EP-104GI is administered as an injection into the esophageal wall, providing local delivery of drug. This is a unique treatment approach for EoE. Eupraxia also recently completed a Phase 2b clinical trial (SPRINGBOARD) of EP-104IAR for the treatment of pain due to knee osteoarthritis. The trial met its primary endpoint and three of the four secondary endpoints. In addition, Eupraxia is developing a pipeline of later and earlier-stage long-acting formulations. Potential pipeline indications include candidates for other inflammatory joint indications and oncology, each designed to improve on the activity and tolerability of currently approved drugs. For further details about Eupraxia, please visit the Company's website at: www.eupraxiapharma.com.

Notice Regarding Forward-looking Statements and Information

This news release includes forward-looking statements and forward-looking information within the meaning of applicable securities laws. Often, but not always, forward-looking information can be identified by the use of words such as "plans", "is expected", "expects", "suggests", "scheduled", "intends", "contemplates", "anticipates", "believes", "proposes", "potential" or variations (including negative and grammatical variations) of such words and phrases, or state that certain actions, events or results "may", "could", "would", "might" or "will" be taken, occur or be achieved. Forward-looking statements in this news release include

statements regarding the Company's product candidates, including expected benefits to patients with respect to safety, efficacy, duration and tolerability; additional clinical data from the RESOLVE trial of EP-104GI in EoE, including the Company's intention to periodically disclose such data and timing thereof; the Company's expectations regarding dose-escalating cohorts; the Company's product candidates, including expected benefits to patients; the results gathered from studies and trials of Eupraxia's product candidates; the potential for the Company's technology to impact the drug delivery process; potential market opportunity for the Company's products, and potential pipeline indications. Such statements and information are based on the current expectations of Eupraxia's management, and are based on assumptions, including but not limited to: future research and development plans for the Company proceeding substantially as currently envisioned; industry growth trends, including with respect to projected and actual industry sales; the Company's ability to obtain positive results from the Company's research and development activities, including clinical trials; and the Company's ability to protect patents and proprietary rights. Although Eupraxia's management believes that the assumptions underlying these statements and information are reasonable, they may prove to be incorrect. The forward-looking events and circumstances discussed in this news release may not occur by certain dates or at all and could differ materially as a result of known and unknown risk factors and uncertainties affecting Eupraxia, including, but not limited to: risks and uncertainties related to the Company's limited operating history; the Company's novel technology with uncertain market acceptance; if the Company breaches any of the agreements under which it licenses rights to its product candidates or technology from third parties, the Company could lose license rights that are important to its business; the Company's current license agreement may not provide an adequate remedy for its breach by the licensor; the Company's technology may not be successful for its intended use; the Company's future technology will require regulatory approval, which is costly and the Company may not be able to obtain it; the Company may fail to obtain regulatory approvals or only obtain approvals for limited uses or indications; the Company's clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates at any stage of clinical development; the Company may be required to suspend or discontinue clinical trials due to side effects or other safety risks; the Company completely relies on third parties to provide supplies and inputs required for its products and services; the Company relies on external contract research organizations to provide clinical and non-clinical research services; the Company may not be able to successfully execute its business strategy; the Company will require additional financing, which may not be available; any therapeutics the Company develops will be subject to extensive, lengthy and uncertain regulatory requirements, which could adversely affect the Company's ability to obtain regulatory approval in a timely manner, or at all; the impact of health pandemics or epidemics on the Company's operations; the Company's restatement of its consolidated financial statements, which may lead to additional risks and uncertainties, including loss of investor confidence and negative impacts on the Company's common share price; and other risks and uncertainties described in more detail in Eupraxia's public filings on SEDAR+ (sedarplus.ca) and EDGAR ([sec.gov](https://www.sec.gov)). Although Eupraxia has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements and information, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. No forward-looking statement or information can be guaranteed. Except as required by applicable securities laws, forward-looking statements and information speak only as of the date on which they are made and Eupraxia undertakes no obligation to publicly update or revise any forward-looking statement or information, whether as a result of new information, future events or otherwise.

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