Eupraxia Doses First Patient in Phase 2b Placebo-Controlled Portion of EP-104GI RESOLVE Trial in Eosinophilic Esophagitis

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- Dosing of the first patient in Phase 2b marks an important transition of the RESOLVE trial from a Phase 2a open-label study to a Phase 2b placebo-controlled study. This is a critical step required prior to proceeding to pivotal clinical trials necessary for regulatory approval
- Eupraxia plans to enroll a minimum of 60 patients in the Phase 2b portion of the RESOLVE study in up to 25 sites globally, assessing tissue health measured by biopsy (EoEHSS and PEC scores), symptom scores (SDI and DSQ), and safety, over a twelve-month period
- The Phase 2b study will be comprised of 3 dose arms - one placebo and two separate active doses of EP-104GI
- Dose selection for the Phase 2b study was based on a comprehensive review of all safety, pharmacokinetic, and efficacy data collected to date in the ongoing open-label Phase 2a study
- Topline data from the Phase 2b portion of the RESOLVE study are expected by Q3 2026
- During the Phase 2b portion of the RESOLVE study, Eupraxia will continue to report additional data from patients that were entered into the open-label Phase 2a study, with further data from cohorts 5–8 available in early September and November of 2025

VICTORIA, British Columbia, July 08, 2025 (GLOBE NEWSWIRE) -- Eupraxia Pharmaceuticals Inc. (“Eupraxia” or the “Company”) (NASDAQ:EPRX) (TSX:EPRX), a clinical-stage biotechnology company leveraging its proprietary DiffuSphere™ technology designed to optimize local, controlled drug delivery for applications with significant unmet need, today announced the first patient dosed in the Phase 2b randomized, placebo-controlled portion of the RESOLVE clinical trial evaluating EP-104GI, an investigational treatment for eosinophilic esophagitis (“EoE”). EP-104GI is injected directly into the affected tissues of the esophagus to reduce inflammation with stable, localized, and long-duration drug delivery, while minimizing unwanted systemic adverse events and side effects often associated with steroid-based therapies.

The Phase 2b portion of the RESOLVE study will enroll a minimum of 60 participants randomized in a 1:1:1 ratio to receive one of two doses of EP-104GI or placebo. After six months, eligible patients initially dosed with placebo may elect to receive EP-104GI. The primary objective is to assess the efficacy of EP-104GI in improving tissue health, as measured by the Eosinophilic Esophagitis Histology Scoring System (“EoEHSS”). Secondary and exploratory objectives include evaluating symptomatic improvement through patient-reported outcomes — Straumann Dysphagia Index score (SDI) and Dysphagia Symptom Questionnaire (DSQ), endoscopic and histologic changes (including Peak Eosinophil Count, “PEC”), pharmacokinetics, safety, and tolerability of the selected dose regimens. Up to 25 sites globally are expected to participate in the trial.

The Phase 2b portion of the study employs an innovative adaptive design to select the doses of EP-104GI that are administered to patients. The first active dose selection was based on available data from cohorts 1 to 8 of the Phase 2a portion of the study. Based on the previously reported safety, pharmacokinetic, and efficacy data from cohorts 1 to 6, and additional one month data from cohorts 7 and 8, the 120 mg dose (20 injections of 6 mg per site) from cohort 8 was selected for the first treatment arm in the dose optimization phase. A second dose will be selected for evaluation after enrollment in the first arm is complete, based on additional long-term data from the Phase 2a portion of the study.

“Entering into the Phase 2b stage of the RESOLVE trial is a significant event for Eupraxia. This is an important step for us before proceeding towards the pivotal trials necessary for submitting an application for regulatory approval,” said James Helliwell, CEO of Eupraxia Pharmaceuticals. “We are optimistic that EP-104GI has the potential to significantly advance the standard of care and offer a meaningful new treatment paradigm for patients living with EoE.”

The RESOLVE Safety Review Committee conducted a comprehensive review of all safety, pharmacokinetic, and efficacy data collected to date in all dose cohorts of the open label study including, importantly, the 4-week data from cohort 8. Based on this review, the Committee expressed confidence in the results from the safety and clinical efficacy outcomes of the cohort 8 dose and recommended its use as the first of the two active doses of the Phase 2b randomized, placebo-controlled portion of the study.

Regarding the early data from cohort 8 that was used to select the initial active dose for the Phase 2b study, Dr Helliwell further

stated, “We are excited about the data we have seen from cohort 8, which represents the largest dose given to date — the efficacy data from the 4-week timepoint are very encouraging. Patients are experiencing the largest and earliest decline in PEC at 4 weeks, and the lowest EoEHSS scores at 4 weeks, of any cohort to date. Additionally, and similar to what was seen with the previous cohorts, there were no serious adverse events, no oral or esophageal candidiasis (“thrush”), and no changes in cortisol or glucose.”

Eupraxia will report further details regarding the histological scores, symptom responses, pharmacokinetic results and safety details for cohorts 7 and 8 once data from the 12-week timepoint from cohort 8 is available, which is expected in Q3 of this year. Additional data from all cohorts from the Phase 2a open label portion will be reported over the coming months and on an ongoing basis during the conduct of the Phase 2b study, as patients progress through their 4, 12, 24, 36 and 52-week timepoints.

Topline data from the Phase 2b portion of the RESOLVE study is expected to be available in Q3 2026.

About the RESOLVE Trial

The RESOLVE trial is a Phase 1b/2, multicenter, two-part study evaluating the safety, tolerability, pharmacokinetics, and efficacy of EP-104GI in adults with active EoE. The treatment is administered as a single dose via esophageal wall injections, with increasing dose per site and/or number of sites in the dose escalation portion of the trial. In the second part of the trial, up to two different doses of EP-104GI will be evaluated versus placebo over 52 weeks of follow-up. Patients will be evaluated for changes in esophageal health (EoEHSS and reductions in PEC) at weeks 12, 24, 36, and 52, and clinical symptoms will be assessed using multiple validated scoring systems, including SDI and DSQ. Additional data from the open-label, dose escalation portion is expected to be released in H2 2025.

About EoE

EoE is an inflammatory disease in which white blood cells migrate to the esophagus, resulting in pain and difficulty swallowing food. According to market research from Clearview Healthcare Partners, 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/2 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 expected enrollment and number of sites for the Phase 2b portion of the RESOLVE study; the expected parameters of the RESOLVE study; the availability of topline data and release of additional long-term data with higher doses and timing thereof; the Company's product candidates, including their expected benefits to patients with respect to safety, tolerability, efficacy and duration; the expectations around proceeding to clinical trials for the Company’s product candidates; 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 product candidates; 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 its 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 product candidates and services; the potential impact of tariffs on the cost of the Company’s active pharmaceutical ingredients and clinical supplies of EP-104IAR and EP-104GI; 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). 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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