Eupraxia Pharmaceuticals Announces Positive Data from Highest-Dose Cohort in the Ongoing RESOLVE Trial in Eosinophilic Esophagitis, and Plans for Expansion of EP-104GI Development Programs

September 29, 2025

- Clinical data was reported for the first time in patients receiving an 8 mg dose per injection (Cohort 9 of the dose escalation portion of RESOLVE), the highest dose planned in this trial.
- Patients in Cohort 9 experienced the largest improvements in tissue health outcomes and eosinophil reduction observed to date.
- RESOLVE Safety Committee and members of the Eupraxia Clinical Advisory Board endorsed using the 8 mg dose per injection as the second dose for the ongoing Phase 2b portion of the RESOLVE study.
- Eupraxia intends to expand the EP-104GI development program, including increasing the number of patients in the Phase 2b portion of RESOLVE from 60 to at least 120 patients.
- Eupraxia intends to initiate a clinical trial for an additional market-expanding GI indication in the first half of 2026.
- Eupraxia will host a webinar on October 1st at 8am PDT to provide additional information. The live webinar is available at: https://lifescievents.com/event/fk30t7wg2n/

VICTORIA, British Columbia, Sept. 29, 2025 (GLOBE NEWSWIRE) -- Eupraxia Pharmaceuticals Inc. (“Eupraxia” or the “Company”) (NASDAQ:EPRX) (TSX:EPRX), a clinical-stage biotechnology company leveraging its proprietary Diffusphere™ technology to optimize local, controlled drug delivery for diseases with significant unmet need, today provided an operational update on the development of EP-104GI, including reporting data from patients in Cohort 9 of the dose escalation portion of the RESOLVE trial, the first time that patients received an 8mg dose per injection.

“We believe our recent financing, combined with our latest clinical trial results, underscores both the medical and investment communities’ confidence in EP-104GI. The strong efficacy trend observed in previous cohorts – the more drug we deliver to the tissue, the better the results we observe – has continued in Cohort 9. Combined with the absence of any Serious Adverse Events or cases of candidiasis, this strongly suggests that an 8mg dose per injection is the optimal second dose to test in our Phase 2b trial”, said Dr. James A. Helliwell, Chief Executive Officer of Eupraxia. “We believe EP-104GI has the potential to significantly improve upon the current standard of care, as the clinical efficacy outcomes and improvements in tissue health reported so far are well beyond the published results for the leading currently approved therapies. With the capital raised, we are well-positioned to expand our Phase 2 study, prepare for a robust Phase 3 program, and pursue additional clinical indications, subject to discussions with FDA, all with a runway extending well into 2028”.

Key Findings from the 8mg Per Injection Dose Group in the Dose Escalation Portion of the RESOLVE Trial

The corporate presentation on the Company’s website has been updated to reflect the additional data described below.

- **Clinical Remission[1]:** Rapid and meaningful induction of clinical remission observed as measured by the Straumann Dysphagia Index (“SDI”) [2]
- **Tissue Health and Eosinophil Reduction:** Greatest improvements to date in EoEHSS (Eosinophilic Esophagitis Histological Scoring System) scores, with the greatest percentage of biopsy sites in remission (≤6 eos/hpf)[3]
- **Correlation to Outcomes:** Across all cohorts, when more drug is delivered into the tissue, greater disease resolution and eosinophil reduction is observed
- **Durability:** Long-term data continues to show patients maintaining clinical benefit, tissue health, and tolerability
- **Safety Outcomes:** Zero SAEs and zero cases of candidiasis reported across all patients, including those at the 8mg per injection dose

Key Changes to The Phase 2b RESOLVE Trial

- Based on the positive safety and efficacy results from Cohort 9 in the open-label dose escalation (Phase 1b/2a study),

Eupraxia expects to select the 8 mg/per injection & 20 injections per administration (for a total for 160 mg per patient) as the second active dose level for the Phase 2b portion of the RESOLVE trial. The dose level has been cleared by the RESOLVE Safety Committee and endorsed by members of the Eupraxia Clinical Advisory Board.

- Eupraxia intends to increase the size of the Phase 2b portion of the RESOLVE Trial to a minimum of 40 patients per dose group. The total number of patients enrolled is expected to increase from 60 to at least 120.
- The increase in size of the Phase 2b trial will provide the following benefits:
    - Greater statistical power to the primary and all key secondary endpoints
    - Larger safety database
    - Improved potential of obtaining breakthrough status
    - Higher probability of needing to perform only a single Phase 3 pivotal trial
    - Improved ability to select an optimized dose for Phase 3 for safety, efficacy and durability

Expanded Plans for EP-104GI and Other New Drug Candidate(s)

In addition to increasing the size of the RESOLVE study, Eupraxia intends to use proceeds from the recent financing to expand the non-clinical and clinical program for EP-104GI, subject to discussions with FDA, with the aim of increasing the future market size of the program. This includes:

- Development of additional indications for EP-104GI in the GI field; the Company plans to dose first patients in the first half of 2026.
- The Company is currently considering indications where localized treatment would provide maximum benefit such as fibrostenotic Crohn's, treatment of benign esophageal strictures, and the prevention of strictures in Barrett's esophagus.
- Completion of non-clinical work to enable repeat dosing and inclusion of adolescent patients in the Phase 3 program.
- Development work of applications for Diffusphere™ with other Active Pharmaceutical Ingredients (APIs) other than fluticasone propionate

About the RESOLVE Trial

The Phase 1b/2a part of the RESOLVE trial, is a multicenter, open-label, dose-escalation study evaluating the safety, tolerability, pharmacokinetics, and efficacy of EP-104GI in adults with histologically confirmed active EoE. The treatment is administered as a single dose via 4 to 20 esophageal wall injections, with dose escalations modifying either the dose per site and/or the number of sites. Participants were followed for up to 24 weeks (4x1mg, 8x1mg, 8x2.5mg and 12x2.5mg) or 52 weeks (12x4mg and subsequent ongoing dose levels). Eupraxia plans to disclose additional data from the open-label Phase 1b/2a part of the RESOLVE trial in Q4 2025.

The Phase 2b part of the RESOLVE trial, a randomized placebo-controlled study of EP-104GI, is currently recruiting with the first clinical dose of 120mg (20 x 6mg). The top-line data from the Phase 2b part of the RESOLVE trial is expected in Q3 2026.

Notes

1. Clinical remission is defined as a reduction of at least 3 points on the SDI scale. Achieving clinical remission is a positive outcome for the RESOLVE trial.
2. 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.
3. In the 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.

About Eosinophilic Esophagitis (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 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 statements 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 expected timing of reporting additional data from the RESOLVE trial in Q4 2025; 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 and the expected timing thereof; the Company’s plans to expand the EP-104GI developmental program, including the increase in the number of patients in the Phase 2b portion of RESOLVE and dosing level to be selected, and the timing and expected benefits thereof; the potential for the Company’s technology to impact the drug delivery process; the expected use of proceeds of the Company’s recent financing; 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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