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

February 25, 2025

- Histological scores and symptom scores continue to improve as EP-104GI dose, and area of esophageal coverage, increase
- Cohort 6 showed the greatest symptom relief scores ("SDI") of all cohorts to date at 12 weeks
- Cohort 6 had the greatest magnitude and percentage change in tissue health scores ("EoEHSS") of any cohort to date at 12 weeks
- Cohort 6 saw the greatest reduction in Peak Eosinophil Count ("PEC") of any cohort to date
- Cohort 5 demonstrated the greatest symptom score reduction (SDI) seen to date at 24 weeks, showing continuously improving symptom relief over that time
- For tissue health (EoEHSS) and PEC there is a clear dose-response from Cohorts 3 to 6, with Cohort 6 showing the greatest response
- No serious adverse events nor any events of oral or gastrointestinal candidiasis were reported in any of the six cohorts
- Cohort 7 is fully enrolled, with 12-week data expected in Q2 2025
- Company to host Webinar to discuss data from RESOLVE trial on Wednesday, February 26th at 11:00am PT (Link to Webinar)

VICTORIA, BC, Feb. 25, 2025 /CNW/ - Eupraxia Pharmaceuticals Inc. ("Eupraxia" or the "Company") (TSX: EPRX) (NASDAQ: EPRX), a clinical-stage biotechnology company specializing in precision local drug delivery, today announced additional positive clinical data from its ongoing RESOLVE Phase 1b/2a trial evaluating EP-104GI for the treatment of 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. The Company's ongoing RESOLVE trial is a Phase 1b/2a, multi-center, open-label, dose-escalation study that is evaluating EP-104GI across multiple patient cohorts by assessing key clinical measurements associated with EoE, including SDI, impact on tissue health (histology) as measured by EoEHSS, and the measurement of peak eosinophil count ("PEC").

"In the RESOLVE trial, positive efficacy and safety outcomes continue to be observed," said Dr. James Helliwell, Chief Executive Officer of Eupraxia. "We believe the positive dose-response data from these first six cohorts clearly demonstrate that precise, localized delivery of EP-104GI at higher doses is leading to further improvements in both tissue health and symptom reductions. Also, no serious adverse events nor events of oral or gastrointestinal candidiasis, commonly seen in EOE patients being treated with steroids, have been observed in any of the first six Cohorts."

"We are highly encouraged by the fact that EP-104GI has demonstrated strong activity despite only being administered to varying portions of the esophagus to this point in the trial. This suggests that maximizing esophageal coverage with EP-104GI could lead to further improvements in histology and symptoms. Based on these observations, and the safety results to date, we intend to further explore the potential treatment effect of EP-104GI at higher dosing levels and over expanded esophageal coverage in the upcoming cohorts. The collective safety and efficacy data from the RESOLVE study continue to demonstrate that EP-104GI has the potential to become a new standard of care for the treatment of EoE, and we look forward to reporting the first set of nine-month data from the RESOLVE study in the second quarter."

Key Findings from the Sixth Cohort of the RESOLVE Trial

Each patient in the sixth cohort received 16 injections of 4 mg EP-104GI (total dose: 64 mg) targeting the lower three-quarters of the esophagus. The results include:

- **Symptom Improvement (SDI):** All three patients reported reduced symptom severity, with peak SDI score reductions of up to 5 points (71%) and an average reduction of 46% (3 points) at 12 weeks.
- **Tissue Health (EoEHSS):** The largest improvement in tissue health observed in any cohort to date, with peak Stage and Grade score reductions of 89% and 88%, respectively, and mean Stage and Grade score reductions of 66% and 65%.
- **Peak Eosinophil Counts (PEC):** Mean 94% reduction in eosinophils across a standard number of biopsy sites within the treated area. There was a mean 62% remission rate across all biopsy sites.
- **Safety:** Plasma fluticasone levels remained predictable and well below published levels for daily asthma treatments, with no serious adverse events reported.

Key Findings from Dose Escalation Data

As the table below demonstrates, there is a clear effect of dose on both patient symptoms (SDI) and tissue health (PEC and EoEHSS). These effects are comparable to, or better, than what has been demonstrated by currently approved treatments for EoE.

Cohort	Number of Injections	Esophageal Coverage (%)	Drug/ Injection	SDI		PEC (12 wks) *		EoEHSS (12 wks) **	
				(12 wks)	(24 wks)	Peak Reduction	Remission Rate	Stage	Grade
3	8	8 cm (~40%)	2.5 mg	-28 %	-17 %	-55 %	19 %	-15 %	-7 %
4	12	12 cm (~60%)	2.5 mg	-45 %	-55 %	-67 %	29 %	-39 %	-37 %
5	12	12 cm (~60%)	4 mg	-41 %	-82 %	-83 %	38 %	-54 %	-54 %
6	16	16 cm (~80%)	4 mg	-46 %	TBD	-94 %	62 %	-66 %	-65 %

* PEC (Peak Eosinophil Count) is reported as peak reduction across a standard number of biopsy sites in the treatment area and remission rate is the percentage of biopsy sites (across all sites) with complete remission (PEC≤6)

** EoEHSS (Eosinophilic Esophagitis Histology Scoring System) is a composite score of various histological inflammatory measures, split into separate metrics of "stage" (extent) and "grade" (severity).

Webinar to discuss results

The Company will host a Webinar this Wednesday, February 26th at 11:00am PT. Please click on the link below to register for the Webinar:

Link to Webinar

About the RESOLVE Trial

The RESOLVE trial is a Phase 1b/2a, 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 four to 20 esophageal wall injections, with dose escalations modifying either the dose per site or the number of sites. Patients in Cohorts 1–4 were evaluated for up to 24 weeks, while patients in Cohorts 5 and beyond are assessed for up to 52 weeks. Eupraxia plans to disclose additional data periodically.

With Cohort 7 fully enrolled, Eupraxia anticipates releasing 12-week data in late Q2 2025.

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. If a biopsy site has less than or equal to 6 eosinophils, that site is considered to be in remission. Remission Rate is the percentage of biopsies that are in remission.

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 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/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", "encouraged", "ongoing", "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 their expected benefits to patients with respect to safety, tolerability, efficacy and duration; 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 plans for future cohorts; the Company's expectations regarding the release of Cohort 7 data; 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 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 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). 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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