Press release

Late-breaking analysis demonstrates characteristics associated with long-term overall survival with Onivyde® regimen in metastatic pancreatic adenocarcinoma

- ***Phase III NAPOLI 3 trial is the largest and has the longest follow-up for an interventional study in metastatic pancreatic adenocarcinoma[1]***
- ***Post-hoc analysis of NAPOLI 3 study determined characteristics associated with long-term survival, with median overall survival of 19.5 months amongst long-term survivors receiving Onivyde® plus oxaliplatin, fluorouracil and leucovorin (NALIRIFOX) regimen as a first-line therapy[2]***
- ***Dose reductions and/or treatment delays for the management of adverse events enabled patients to stay on treatment longer and achieve high cumulative doses of liposomal irinotecan and oxaliplatin[2]***

PARIS, France, 31 May 2025 – Late-breaking (LBA4175) post-hoc analysis data from the Phase III NAPOLI 3 study were presented today at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. These results found a median overall survival (mOS) of 19.5 months among long-term survivors (n=15) with metastatic pancreatic adenocarcinoma (mPDAC) treated with the Onivyde® (irinotecan liposome injection) plus oxaliplatin, fluorouracil and leucovorin (NALIRIFOX) regimen as a first-line treatment (n=120), with younger age at diagnosis, and certain tumor and metastasis locations associated with long-term survivorship.[2]

Pancreatic adenocarcinoma (PDAC) is the most common type of cancer that forms in the pancreas, with more than 60,000 people diagnosed annually in the U.S. and nearly 500,000 people globally.[3,4] It is often detected after the disease has spread to other parts of the body (metastatic or stage IV)[5] and fewer than 20% of people diagnosed with metastatic pancreatic adenocarcinoma (mPDAC) survive longer than one year.[5,6] Overall, pancreatic cancer has the lowest five-year survival rate of all cancer types globally and in the U.S.[5,6]

“When people are diagnosed with metastatic pancreatic adenocarcinoma, the most important question remains: how long will they have with their loved ones,” said Dr. Vincent Chung, Medical Oncologist, City of Hope. “Findings from the NAPOLI 3 post-hoc analysis provide important context on long-term overall survival with the Onivyde (NALIRIFOX) treatment regimen.”

The analysis included patients who survived for 18 months or longer (N=15), with findings showing long-term survivors living with mPDAC had a mOS of 19.5 months (interquartile range [IQR]: 18.8–22.6).[2] Clinical and pathological factors of long-term survivors included younger than average age at time of diagnosis (median age 61.0 (IQR: 49.0–70.5) as well as tumor location.[2] Fewer patients had tumors in the head or tail of the pancreas (53.3% had the main pancreatic tumor located in the body of the pancreas), a substantial proportion had liver metastasis (66.7%) and ≥3 metastatic sites (53.3%).[2] Additionally, findings indicate dose reduction and treatment delays resulted in prolonged exposure and higher cumulative doses of the Onivyde (NALIRIFOX) regimen.[1] Liver metastasis and ≥3 metastatic sites, dose modifications and an otherwise good clinical profile enabled people to achieve a long mOS.[2] Consideration should be taken when interpreting these results as a post-hoc analysis with a small sample size.

"Data from the Phase III NAPOLI 3 trial were the first positive data of its kind in a decade and continue to reinforce the potential for long-term outcomes with the Onviyde (NALIRIFOX) regimen,” said Sandra Silvestri, MD, PhD, Executive Vice President, Chief Medical Officer, Ipsen. “With people on average living just 4-6 months following diagnosis with pancreatic adenocarcinoma, these data help us to

understand the characteristics associated with long-term survival seen in the NAPOLI trial, an important advancement for this difficult-to-treat cancer where data of this kind are scarce."

ENDS

About Onivyde (irinotecan liposome injection)

Onivyde is a long-circulating liposomal topoisomerase inhibitor. In Onivyde, irinotecan is enclosed in tiny fat particles called liposomes which accumulate in the tumor and release slowly over time.

Onivyde is administered via intravenous infusion over 90 minutes every two weeks with recommendations on dosing modifications. Onivyde, as part of the NALIRIFOX regimen (combined with oxaliplatin, fluorouracil (FU) and leucovorin (LV)), is for people living with mPDAC who are treatment naïve or used in combination with FU and LV following gemcitabine-based therapy. Onivyde is not indicated as a single agent for the treatment of adult patients with metastatic pancreatic adenocarcinoma.

Ipsen has exclusive commercialization rights for the current and potential future indications for Onivyde in the U.S. Servier, an independent international pharmaceutical company governed by a foundation and with an international presence in 140 countries, is responsible for the commercialization of Onivyde outside of the U.S., Taiwan and Canada. PharmaEngine is a commercial stage oncology company headquartered in Taipei and is responsible for the commercialization of Onivyde in Taiwan.

About NAPOLI 3 Study

NAPOLI 3 is a randomized, open-label Phase III trial of an Onivyde treatment regimen (NALIRIFOX) in treatment-naïve mPDAC. NAPOLI 3 enrolled 770 patients across 187 trial site locations in 18 countries across Europe, North America, South America, Asia, and Australia. Patients were randomized to receive Onivyde plus oxaliplatin, fluorouracil and leucovorin (NALIRIFOX regimen; n=383) twice in a month (days 1 and 15 of 28-day cycle) compared to an injection of nab-paclitaxel and gemcitabine (n=387) administered three times a month (days 1, 8, 15 of a 28-day cycle).

About Ipsen

We are a global biopharmaceutical company with a focus on bringing transformative medicines to patients in three therapeutic areas: Oncology, Rare Disease and Neuroscience.

Our pipeline is fueled by external innovation and supported by nearly 100 years of development experience and global hubs in the U.S., France and the U.K. Our teams in more than 40 countries and our partnerships around the world enable us to bring medicines to patients in more than 100 countries.

Ipsen is listed in Paris (Euronext: IPN) and in the U.S. through a Sponsored Level I American Depositary Receipt program (ADR: IPSEY). For more information, visit ipsen.com.

Ipsen Media contacts

Investors

- **Khalid Deojee | +33 666019526 | khalid.deojee@ipsen.com**

Media

- **Sally Bain | +1 8573200517 | sally.bain@ipsen.com**
- **Anne Liontas | +33 0767347296 | anne.liontas.ext@ipsen.com**

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References

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[3] American Cancer Society – Cancer Facts and Figures 2024. Available : https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2024/2024-cancer-facts-and-figures-acs.pdf

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