Press release

Intended for international media and investor audiences only

Ipsen provides update on CONTACT-02 Phase III trial in metastatic castration-resistant prostate cancer following final overall survival analysis

- ***Trial investigating Cabometyx® (cabozantinib) in combination with atezolizumab demonstrated a positive trend towards improvement for one of the primary endpoints of overall survival, but did not meet statistical significance***
- ***Ipsen will not pursue regulatory submissions for the combination regimen in countries where we have commercialization rights (outside of the US and Japan)***
- ***We remain confident in the proven profile of Cabometyx as a monotherapy and in combination with immunotherapy, across approved and potential future indications***

PARIS, FRANCE, 15 September 2024 - Ipsen (Euronext: IPN; ADR: IPSEY) announced today detailed final overall survival (OS) data from the Phase III CONTACT-02 trial investigating the combination of Cabometyx® (cabozantinib) and atezolizumab in metastatic castration-resistant prostate cancer (mCRPC). The trial investigated the combination regimen versus a second novel hormonal therapy (NHT) in men previously treated with one NHT and measurable soft-tissue disease. At a median follow-up of 24.0 months, these data demonstrated a numerical but not statistically significant improvement in OS for the combination versus a second NHT (hazard ratio: 0.89; 95% confidence interval: 0.72-1.10; P=0.296). As previously announced, the trial met the other primary endpoint of progression-free survival (PFS), demonstrating a statistically significant benefit in PFS.[1] Safety for the combination appeared to be consistent with the known safety profiles of the individual medicines, and no new safety signals were identified.

Based on the results of the final OS analysis and anticipated challenging regulatory environment in the countries in which Ipsen has commercialization rights (outside the US and Japan), Ipsen will not pursue regulatory submissions for this combination regimen in mCRPC.

We remain confident, in the proven profile of Cabometyx as a monotherapy and in combination with immunotherapy across approved indications, as well as its ongoing future potential.

Ipsen wishes to thank the patients, their families and healthcare teams for their participation in this clinical trial.

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About Cabometyx

Cabometyx (cabozantinib) is a small molecule that inhibits multiple receptor tyrosine kinases, including VEGFRs, MET, RET and the TAM family (TYRO3, MER, AXL).[2] These receptor tyrosine kinases are involved in both normal cellular function and pathologic processes such as oncogenesis, metastasis, tumor angiogenesis (the growth of new blood vessels that tumors need to grow), drug resistance, modulation of immune activities and maintenance of the tumor microenvironment.[2,3,4,5]

Exelixis granted Ipsen exclusive rights for the commercialization and further clinical development of Cabometyx outside of the U.S. and Japan. Exelixis granted exclusive rights to Takeda Pharmaceutical Company Limited (Takeda) for the commercialization and further clinical development of Cabometyx for all future indications in Japan. Exelixis holds the exclusive rights to develop and commercialize Cabometyx in the U.S.

In over 65 countries outside of the United States and Japan, including in the European Union, Cabometyx is currently indicated as a:[3]

- Monotherapy for advanced renal cell carcinoma (aRCC).
  - as first-line treatment of adults with intermediate- or poor-risk disease.
  - in adults following prior VEGFR-targeted therapy.
- A combination with nivolumab for the first-line treatment of aRCC in adults.
- Monotherapy for the treatment of adults living with locally advanced or metastatic differentiated thyroid carcinoma, refractory or not eligible to radioactive iodine who have progressed during or after prior systemic therapy.
- Monotherapy for the treatment of hepatocellular carcinoma in adults who have previously been treated with sorafenib.

The detailed recommendations for the use of Cabometyx are described in the Summary of Product Characteristics (EU SmPC).

About mCRPC

Prostate cancer is the second most common cancer in men and the fourth most common cancer overall globally.[6] In 2020, there were more than 1.4 million new cases of prostate cancer and about 375,300 deaths worldwide.[6] Prostate cancer is considered mCRPC when it has spread beyond the prostate and does not respond to androgen-suppression therapies, a common treatment for prostate cancer.[7] Men diagnosed with mCRPC often have a poor prognosis, with an estimated survival of 1-2 years.[8]

About CONTACT-02

CONTACT-02 is a global, multicenter, randomized, Phase III, open-label study that enrolled 575 patients who were randomized 1:1 to the experimental arm of Cabometyx in combination with atezolizumab and the control arm of a second NHT (either abiraterone and prednisone or enzalutamide). The study included patients with mCRPC who have measurable extra-pelvic soft tissue metastasis and who have progressed on one prior NHT. The two primary endpoints of the trial are progression-free survival (PFS) and OS. The PFS analysis was conducted in the first 400 randomized patients (PFS in the intent-to-treat [ITT] population) and assessed by a blinded independent radiology committee (BIRC) per RECIST 1.1. The OS analysis was conducted in the ITT population (n=507). The secondary endpoint is objective response rate (ORR) per BIRC. The trial is sponsored by Exelixis and co-funded by Ipsen, Roche and Takeda. Takeda is conducting the trial in Japan. More information about CONTACT-02 is available at ClinicalTrials.gov.

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 80 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.

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References

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