Deciphera Pharmaceuticals, Inc. Announces Publication of INTRIGUE Phase 3 Clinical Study Results in Journal of Clinical Oncology

August 10, 2022

– Efficacy Observed with QINLOCK® was Comparable to Sunitinib with a More Favorable Safety and Tolerability Profile in GIST Patients Previously Treated with Imatinib –

WALTHAM, Mass.--(BUSINESS WIRE)--Aug. 10, 2022-- Deciphera Pharmaceuticals, Inc. (NASDAQ: DCPH), a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines to improve the lives of people with cancer, today announced that the *Journal of Clinical Oncology* has published results from its INTRIGUE Phase 3 study of QINLOCK® (ripretinib) in patients with advanced gastrointestinal stromal tumor (GIST) previously treated with imatinib. Although QINLOCK did not offer a statistically significant improvement in progression-free survival (PFS) compared to sunitinib, QINLOCK showed meaningful clinical activity with fewer Grade 3/4 treatment-emergent adverse events (TEAEs) and improved tolerability.

The article, titled “Ripretinib versus sunitinib in patients with advanced gastrointestinal stromal tumor after treatment with imatinib (INTRIGUE): A randomized, open-label, phase III trial” is now available online and will be published in a future print issue of the *Journal of Clinical Oncology*.

“These full Phase 3 INTRIGUE study results continue to deepen our understanding of QINLOCK and its place in the GIST treatment landscape,” said Matthew L. Sherman, M.D., Chief Medical Officer of Deciphera. “Although the INTRIGUE study did not meet its primary endpoint of superiority in PFS compared to sunitinib for patients in the post-imatinib setting, the efficacy of QINLOCK was comparable to sunitinib. In addition, QINLOCK had a more favorable safety profile than sunitinib with fewer Grade 3/4 adverse events and patients in the QINLOCK arm reported less deterioration in role functioning and better outcomes on several other key patient-reported outcome measures of tolerability compared to sunitinib.”

INTRIGUE is an international, multi-center study conducted in 122 active sites across 22 countries, where 453 patients with second-line GIST were randomized to receive ripretinib (n=226) or sunitinib (n=227). Key study results include:

- In patients with a KIT exon 11 primary mutation, ripretinib demonstrated a median PFS (mPFS) of 8.3 months compared to 7.0 months for the sunitinib arm (Hazard Ratio [HR] 0.88, p=0.36). In the intention-to-treat (ITT) population (n=453), ripretinib demonstrated an mPFS of 8.0 months compared to 8.3 months for the sunitinib arm (HR 1.05, nominal p value=0.72).
- In patients with a KIT exon 11 primary mutation, ripretinib demonstrated an objective response rate (ORR) of 23.9% (n=39 of 163) compared to 14.6% (n=24 of 164) for sunitinib (nominal p value=0.03). In the ITT population, ripretinib demonstrated an ORR of 21.7% (n=49 of 226) compared to 17.6% (n=40 of 227) for sunitinib (nominal p value=0.27).
- Ripretinib was generally well tolerated. Fewer patients in the ripretinib arm experienced Grade 3/4 treatment-emergent adverse events compared to sunitinib (41.3% vs 65.6%).
- Patients receiving sunitinib were three times more likely to develop Grade 3 hypertension compared to patients receiving ripretinib (26.7% vs. 8.5%) and patients receiving sunitinib were seven times more likely to develop Grade 3 palmar-plantar erythrodysesthesia compared to patients receiving ripretinib (10.0% vs. 1.3%).
- Patient reported outcome measures also showed a more favorable tolerability profile for patients receiving ripretinib compared to patients receiving sunitinib. Patients receiving ripretinib experienced less deterioration in their ability to engage in either work or leisure activities during treatment, and fewer patients receiving ripretinib experienced moderate to extremely large impact on their lives due to skin toxicity across treatment cycles compared to patients receiving sunitinib.

QINLOCK is approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with advanced GIST who have received prior treatment with three or more kinase inhibitors, including imatinib. The new drug application (NDA) for QINLOCK was based on positive results from the Phase 3 INVICTUS trial in patients with fourth-line and fourth-line plus GIST[1].

About QINLOCK (ripretinib)
QINLOCK is a switch-control tyrosine kinase inhibitor that was engineered to broadly inhibit KIT and PDGFRA mutated kinases by using a dual mechanism of action that regulates the kinase switch pocket and activation loop. QINLOCK inhibits primary and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18 involved in GIST, as well as the primary exon 17 D816V mutation[2,3]. QINLOCK also inhibits primary PDGFRA mutations in exons 12, 14, and 18, including the exon 18 D842V mutation, involved in a subset of GIST[2,3].

About Deciphera Pharmaceuticals
Deciphera is a biopharmaceutical company focused on discovering, developing, and commercializing important new medicines to improve the lives of people with cancer. We are leveraging our proprietary switch-control kinase inhibitor platform and deep expertise in kinase biology to develop a broad portfolio of innovative medicines. In addition to advancing multiple product candidates from our platform in clinical studies, QINLOCK® is Deciphera’s switch control inhibitor for the treatment of fourth-line GIST. QINLOCK is approved in Australia, Canada, China, the European Union, Hong Kong, Switzerland, Taiwan, the United Kingdom, and the United States. For more information, visit www.deciphera.com and follow us on LinkedIn and Twitter (@Deciphera).

References

1. Blay JY, Serrano C, Heinrich MC et al. Ripretinib in patients with advanced gastrointestinal stromal tumours (INVICTUS): A double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol* 2020; 21:923–934.
2. Smith B et al., Ripretinib (DCC-2618) is a switch control kinase inhibitor of a broad spectrum of oncogenic and drug-resistant KIT and PDGFRA variants. *Cancer Cell* 2019; 35:738–751.
3. Bauer S, Heinrich M, et al. Clinical activity of ripretinib in patients with advanced gastrointestinal stromal tumor harboring heterogenous KIT/PDGFRA mutations in the phase 3 INVICTUS study. *Clinical Cancer Research* 2021; 27:6333-6342.

View source version on businesswire.com: https://www.businesswire.com/news/home/20220810005609/en/

Investor Relations:
Maghan Meyers
Argot Partners
Deciphera@argotpartners.com
212-600-1902

Media:
David Rosen
Argot Partners
david.rosen@argotpartners.com
212-600-1902

Source: Deciphera Pharmaceuticals, Inc.