



NiKang Therapeutics and AVEO Oncology Announce a Clinical Trial Collaboration and Supply Agreement to Evaluate the Combination of NKT2152, a HIF2 α Inhibitor, and FOTIVDA[®] (tivozanib) for the Treatment of Advanced Clear Cell Renal Cell Carcinoma

January 5, 2022

- Phase 2 Clinical Trial Targeted to Commence in 2022 -

WILMINGTON, Del. & BOSTON--(BUSINESS WIRE)--Jan. 5, 2022-- NiKang Therapeutics Inc. ("NiKang"), a clinical stage biotech company focused on developing innovative small molecule oncology medicines to help patients with unmet medical needs and AVEO Oncology (Nasdaq: AVEO), a commercial stage, oncology-focused biopharmaceutical company ("AVEO"), today announced that they have entered into a clinical trial collaboration and supply agreement to evaluate NKT2152, NiKang's small molecule that inhibits hypoxia inducible factor 2 α (HIF2 α), in combination with FOTIVDA[®] (tivozanib), AVEO's oral, next-generation vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI), which is approved by the U.S. Food and Drug Administration (FDA) for the treatment of adults with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. The phase 2 clinical trial will evaluate the safety and efficacy of the combination of NKT2152 and tivozanib in clear cell RCC (ccRCC) patients who have not responded to or relapsed from prior therapies (R/R RCC). Under the terms of the agreement, NiKang will sponsor the trial and AVEO will co-fund the trial. Both companies will provide its respective drugs at no cost. The two companies will form a Joint Development Committee to oversee this collaboration.

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"Preclinical and early clinical data have demonstrated enhanced anti-tumor activity by the combination of HIF2 α and VEGFR inhibition. Given tivozanib's established excellent clinical profile, we are excited to work with AVEO to explore such opportunity," said Zhenhai Gao, Ph.D., Co-founder, President and Chief Executive Officer of NiKang. "We look forward to collaborating with our partners to further advance NKT2152 into its next stage of development as part of our combination strategy. This clinical collaboration with AVEO is an excellent example of pooling expertise and resources together to maximize the potential of both NKT2152 and tivozanib in helping R/R ccRCC patients."

"This collaboration with NiKang, will play an important role in the advancement of both the tivozanib and NKT2152 programs," said Michael Bailey, President and Chief Executive Officer of AVEO. "The tivozanib and NKT2152 combination will build on the activity seen with VEGFR TKIs and HIF2 α agents in ccRCC. We believe the best-in-class qualities of these two compounds provide a unique combination of efficacy and tolerability for patients with R/R ccRCC as a doublet or, potentially in the future, as part of a triple combination."

The phase 2 clinical trial is expected to commence in 2022.

About NKT2152

NKT2152 is a small molecule that inhibits HIF2 α . It is currently in a phase 1/2 dose escalation and expansion trial (NCT05119335). This trial is designed to evaluate safety, tolerability, pharmacokinetics, pharmacodynamics and clinical activity in patients with advanced ccRCC. Once an appropriate dose is identified, combination studies including NKT2152 will commence.

About NiKang Therapeutics

NiKang Therapeutics is a clinical stage biotech company focused on discovering and developing innovative small molecule oncology medicines to help patients with unmet medical needs. Our target selection is driven by deep insights into disease biology and molecular pathways. Our discovery approach is informed by target structure biology and capitalizes on structure-based drug design. The successful implementation of our strategy enables us to rapidly and efficiently discover and advance proprietary drugs. For more information, [visit www.nikangtx.com](http://www.nikangtx.com).

About FOTIVDA[®] (tivozanib)

FOTIVDA[®] (tivozanib) is an oral, next-generation vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI). It is a potent, selective inhibitor of VEGFRs 1, 2, and 3 with a long half-life designed to improve efficacy and tolerability. AVEO received U.S. Food and Drug Administration (FDA) approval for FOTIVDA on March 10, 2021 for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. FOTIVDA was approved in August 2017 in the European Union and other countries in the territory of its partner EUSA Pharma (UK) Limited for the treatment of adult patients with advanced RCC. FOTIVDA has been shown to significantly reduce regulatory T-cell production in preclinical models.¹ FOTIVDA was discovered by Kyowa Kirin.

About AVEO Pharmaceuticals, Inc.

AVEO is a commercial-stage, oncology-focused biopharmaceutical company committed to delivering medicines that provide a better life for patients with cancer. AVEO currently markets FOTIVDA[®] (tivozanib) in the U.S. for the treatment of adult patients with relapsed or refractory renal cell carcinoma (RCC) following two or more prior systemic therapies. AVEO continues to develop FOTIVDA in immuno-oncology combinations in RCC and

other indications, and has other investigational programs in clinical development. AVEO is committed to creating an environment of diversity, equity and inclusion to diversify representation within the Company.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements of AVEO within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. The words "anticipate," "believe," "design," "expect," "hope," "intend," "may," "plan," "potential," "could," "should," "would," "seek," "look forward," "advance," "goal," "strategy," or the negative of these terms or other similar expressions, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements about: the potential efficacy, safety, tolerability and clinical utility of NKT2152 and tivozanib, each as stand-alone drug candidates and/or in combination with one another in ccRCC and other indications; the anticipated commencement date for the phase 2 clinical trial; the potential outcomes from the trial in NKT2152 and tivozanib to provide NiKang and/or AVEO with opportunities to pursue regulatory strategies; NiKang's strategy, prospects, plans and objectives for NKT2152 and its other product candidates and for NiKang generally; and AVEO's strategy, prospects, plans and objectives for tivozanib and its other product candidates and for AVEO generally. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that AVEO makes due to a number of important factors, including risks relating to: Each of NiKang's and AVEO's ability and collaboration, to demonstrate to the satisfaction of applicable regulatory agencies such as the FDA the safety, efficacy, and clinically meaningful benefit of NKT2152 tivozanib, as stand-alone drug candidates and/or in combination with one another in ccRCC and other indications; risks relating to the timing and costs of seeking and obtaining regulatory approvals; AVEO's dependence on third-party vendors for the development, manufacture, supply, storage and distribution of tivozanib; the potential adverse effects of the COVID-19 pandemic on the ability to successfully enroll the phase 2 clinical trial in R/R ccRCC patients; AVEO's business continuity, financial condition, results of operations, liquidity and ability to commercialize FOTIVDA, manufacture clinical and commercial product and timely initiate new trials or complete its ongoing clinical trials; competitive factors; and those risks discussed in the sections titled "Risk Factor Summary," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" included in AVEO's quarterly and annual reports on file with the Securities and Exchange Commission (SEC) and in other filings that AVEO makes with the SEC. The forward-looking statements in this press release represent AVEO's views as of the date of this press release, and subsequent events and developments may cause its views to change. While AVEO may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. You should, therefore, not rely on these forward-looking statements as representing AVEO's views as of any date other than the date of this press release.

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