Surface Oncology Announces FDA Fast Track Designation Granted by U.S. Food and Drug Administration for SRF388 to Treat Liver Cancer

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CAMBRIDGE, Mass., Nov. 11, 2020 (GLOBE NEWSWIRE) -- Surface Oncology (Nasdaq: SURF), a clinical-stage immuno-oncology company developing next-generation immunotherapies that target the tumor microenvironment, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to SRF388 for the treatment of patients with hepatocellular carcinoma (HCC), or liver cancer, who have been previously treated with standard therapies, such as vascular endothelial growth factor targeted agents and programmed death-ligand (PD-L1) blockade.

“Liver cancer is the most rapidly increasing type of cancer in both men and women in the U.S., with incidences tripling since 1980.1 2 There is a significant need to expedite the development of new therapies to treat liver cancer as the five-year survival for patients with unresectable or metastatic liver cancer is less than five percent,” said Rob Ross, M.D., chief medical officer. “SRF388 targets IL-27, an immuno-suppressive cytokine that has been found to be elevated in patients with liver cancer, as well as kidney cancer, and we believe SRF388 has the potential to be an effective treatment option for these patients, as monotherapy or in combination with anti-PD-1 therapies.”

SRF388 is currently enrolling patients with advanced solid tumors in a Phase 1 monotherapy dose escalation study with planned expansions in liver and kidney cancer to further evaluate SRF388 as a monotherapy and in combination with other cancer therapies.

The FDAs Fast Track designation is designed to facilitate the development and expedite the review of drugs that are being developed to treat serious conditions and fill an unmet medical need. The purpose of the designation is to bring important new drugs to patients earlier across a wide range of diseases.

SRF388 recently received orphan-drug designation for treatment of hepatocellular carcinoma from the FDA.

About SRF388:

SRF388 is a fully human anti-IL-27 antibody designed to inhibit the activity of this immuno-suppressive cytokine. Surface Oncology has identified particular tumor types, including liver and kidney cancer, where IL-27 appears to play an important role in the immuno-suppressive tumor microenvironment and may contribute to resistance to treatment with checkpoint inhibitors. SRF388 targets the rate-limiting p28 subunit of IL-27, and preclinical studies have shown that treatment with SRF388 blocks the immuno-suppressive biologic effects of IL-27, resulting in immune cell activation in combination with other cancer therapies and potent anti-tumor effects as a monotherapy. Furthermore, Surface Oncology has identified a potential biomarker associated with IL-27 that may be useful in helping identify patients most likely to respond to SRF388.

About Surface Oncology:

Surface Oncology is an immuno-oncology company developing next-generation antibody therapies focused on the tumor microenvironment. Its pipeline includes two wholly-owned lead programs targeting CD39 (SRF617) and IL-27 (SRF388), a clinical-stage collaboration with Novartis targeting CD73 (NZV930), and two preclinical programs, each focused primarily on activating natural killer cells (via targeting PVRIG, also known as CD112R (SRF813)), or depleting regulatory T cells (via targeting CCR8 (SRF114)). Surface’s novel cancer immunotherapies are designed to achieve a clinically meaningful and sustained anti-tumor response and may be used alone or in combination with other therapies. For more information, please visit www.surfaceoncology.com.

Cautionary Note Regarding Forward-Looking Statements:

Certain statements set forth in this press release constitute “forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements can be identified by terms such as “believes,” “expects,” “plans,” “potential,” “would,” or similar expressions, and the negative of those terms. These forward-looking statements are based on Surface Oncology’s management’s current beliefs and assumptions about future events and on information currently available to management.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Surface Oncology’s actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks include, but are not limited to, risks and uncertainties related to Surface Oncology’s ability to successfully develop SRF388, SRF617, SRF813 and its other product candidates through current and future milestones or regulatory filings on the anticipated timeline, if at all, the therapeutic potential of Surface Oncology’s product candidates, the risk that results from preclinical studies or early clinical trials may not be representative of larger clinical trials, the risk that Surface Oncology’s product candidates, including SRF388, SRF617 and SRF813, will not be successfully developed or commercialized, the risks related to Surface Oncology’s dependence on third-parties in connection with its manufacturing, clinical trials and preclinical studies, and the potential impact of COVID-19 on our clinical and preclinical development timelines and results of operations. Additional risks and uncertainties that could affect Surface Oncology’s future results are included in the section titled “Risk Factors” in our Annual Report on Form 10-K for the year ending December 31, 2019 and our Quarterly Report on Form 10-Q for the quarter ending March 31, 2020, both of which are available on the Security and Exchange Commission’s website at www.sec.gov and Surface Oncology’s website at www.surfaceoncology.com.

Additional information on potential risks will be made available in other filings that Surface Oncology makes from time to time with the Securities and Exchange Commission. In addition, any forward-looking statements contained in this press release are based on assumptions that Surface Oncology believes to be reasonable as of this date. Except as required by law, Surface Oncology assumes no obligation to update these forward-looking
statements, or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

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