RestorGenex Granted Orphan Drug Designation for RES-529 for Treatment of Glioblastoma Multiforme

BUFFALO GROVE, Ill., Jan. 28, 2015 (GLOBE NEWSWIRE) -- RestorGenex Corporation (RESX), a specialty biopharmaceutical company focused on developing products for oncology, ophthalmology and dermatology, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for RES-529 for the treatment of glioblastoma multiforme. Orphan drug designation, as granted by the U.S. Orphan Drug Act, is for a product to treat a rare disease or condition that affects fewer than 200,000 people in the United States. Orphan drug designation qualifies the sponsor of the product for a tax credit and seven years of marketing exclusivity.

"We are pleased that the FDA has granted RES-529 orphan drug status to treat glioblastoma multiforme as this disease is a tremendous unmet medical need, and thus far has been challenging for drug development. This represents a significant regulatory milestone for RestorGenex," said Stephen M. Simes, chief executive officer of RestorGenex. "RES-529 is an inhibitor of both TORC1 and TORC2 mechanistically differentiated from other PI3K pathway inhibitors currently in development. We have shown activity in both in vitro and in vivo glioblastoma animal models, and we plan to complete necessary work to start a Phase I/II glioblastoma human clinical trial in 2016."

RES-529 is a first-in-class inhibitor of the PI3K/Akt/mTOR pathway. Signaling components of the PI3K pathway are central regulators of cell proliferation, growth, differentiation, survival and angiogenesis. Up to 80 percent of tumor types have been shown to have an aberrant up-regulation of the PI3K pathway. Activation of this pathway has been observed in glioblastoma patients thus making PI3K pathway inhibition a validated target for therapeutic intervention in glioblastoma multiforme.

About RES-529

RES-529 was developed from a non-steroidal, small molecule drug library through computational design, synthetic and medicinal chemistry. RES-529 is the result of three generations of design work. Through a series of in vitro and in vivo animal models, RES-529 has been shown to have activity in several cancer types due to its ability to target and inhibit the PI3K/Akt/mTOR signal transduction pathway, specifically as a first-in-class allosteric, dissociative inhibitor of both TORC1 and TORC2.

About RestorGenex Corporation

RestorGenex is a specialty biopharmaceutical company focused on developing a portfolio of first-in-class therapeutic products to treat diseases across the ophthalmologic, oncologic and dermatologic space. RestorGenex's lead product is a novel PI3K/Akt/mTOR pathway inhibitor which has completed two Phase I clinical trials for age-related macular degeneration and is in pre-clinical development for glioblastoma multiforme. The current pipeline also includes a "soft" anti-androgen compound for the treatment of acne vulgaris. RestorGenex's novel inhibition of the PI3K pathway and unique targeting of the androgen receptor show promise in a number of additional diseases, which the Company is evaluating for the purpose of creating safe and effective treatments and innovative therapies. For additional information please see: www.restorgenex.com.

Forward-Looking Statements

Certain statements in this release are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about RestorGenex's plans to complete formulation work and toxicity studies during 2015 and to begin a Phase I/II trial in 2016 and other statements that are not historical in nature, particularly those that utilize terminology such as "plans," "will," "believes," "may," "intends," "expects," "future," "continue," "show promise," other words of similar meaning, derivations of such
words and the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Risks and uncertainties may cause RestorGenex's actual results to be materially different than those expressed in or implied by such forward-looking statements. Particular risks and uncertainties include, among others, uncertainties involved in clinical testing, the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance, RestorGenex's ability to license out its existing products and technologies and license in additional products and technologies and the terms of such licenses; and other risks and uncertainties described in RestorGenex's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K/A, subsequent quarterly reports on Form 10-Q and final prospectus dated July 31, 2014. All forward-looking statements in this release speak only as of the date of this release and are based on RestorGenex's current beliefs and expectations. RestorGenex undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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