Myrexis Reports Phase 1 Clinical Results for Hsp90 Inhibitor Program

SALT LAKE CITY, Nov. 14, 2011 (GLOBE NEWSWIRE) -- Myrexis, Inc. (Nasdaq:MYRX), a biotechnology company focused on the development of small molecule therapeutics with novel chemical structures and distinct mechanisms of action, today announced that it presented two posters at the 2011 European Organization for Research and Treatment of Cancer (EORTC), National Cancer Institute (NCI) and American Association for Cancer Research (AACR) Symposium on "Molecular Targets and Cancer Therapeutics" in San Francisco, CA.

In a poster titled, "Phase 1 Study of Hsp90 Inhibitor MPC-3100 in Subjects with Refractory or Recurrent Cancer," Phase 1 clinical results were presented for MPC-3100, the Company's lead candidate in its fully synthetic, orally bioavailable heat shock protein 90 (Hsp90) inhibitor program, which also includes the alanine prodrug of MPC-3100, MPC-0767.

The phase 1 study was an open-label, dose-escalating, multiple-dose, study in which 26 patients with recurrent cancer or cancer refractory to available systemic therapy were treated with MPC-3100. The study demonstrated that MPC-3100 was generally safe and well tolerated at doses below 600 mg per day. The most common adverse events were gastrointestinal, including diarrhea, nausea, and vomiting. Pharmacokinetic analysis indicated that the Cmax and AUC(0-12h) increased proportionally to the dose of MPC-3100. The terminal plasma half-life of MPC-3100 ranged from 4.8 to 21.4 hours with a mean half-life of 11.2 hours. The best clinical response was stable disease (12/26; 46%), with a median duration of 11.1 weeks (range 3.0-52.3 weeks). On target activity of MPC-3100 was confirmed by biomarker analysis, which suggested effective and persistent in vivo inhibition of Hsp90. The Company is currently evaluating plans to initiate a Phase 2a study of MPC-3100 in a population of patients with acute myelogenous leukemia (AML) in the second quarter of 2012.

In a second poster titled, "Pharmacokinetics, Anti-Tumor Activity and Therapeutic Index of Nampt Inhibitor MPC-8640 in Mice," Myrexis presented data from MPC-8640, the lead compound in its preclinical nicotinamide phosphoribosyltransferase (Nampt) inhibitor program. MPC-8640 is a potent, selective, and orally bioavailable small molecule inhibitor, designed as a prodrug to increase solubility and convert to active drug following oral administration.

Mice with HT1080 human fibrosarcoma xenograft tumors were treated orally with MPC-8640 on either a once-daily or twice-daily dosing schedule. After one week of treatment, the mice demonstrated complete tumor growth inhibition at lower doses and substantial tumor regression at higher doses. Significantly, tumor regression could be achieved well below the maximum tolerated dose of MPC-8640 and the anti-tumor response observed after one week of dosing was maintained for at least one week without further treatment. The results also demonstrated that MPC-8640 is effectively converted into active Nampt inhibitor. This conversion occurs either in the gut or immediately upon absorption, as evidenced by the lack of significant plasma concentrations of intact MPC-8640, even when dosed greater than three times the maximum tolerated dose.

Taken together, these results demonstrate that treatment with MPC-8640 is an effective mode of delivery of active Nampt inhibitor and that administration of this drug results in significant antitumor activity in animal models of cancer.

About the MPC-3100 Phase 1 Study

The first-in-human, open label, dose escalating, multi-dose, Phase 1 study enrolled a total of 26 patients aged 45-85 years with recurrent or refractory cancer. Patients received oral MPC-3100 either once daily for 21 days followed by seven days off (cohorts 1-5, at doses of 50, 100, 165, 245, and 340mg/m², respectively) or continuously for a 28-day cycle at doses spaced 12 hours apart (cohorts 6-7, at total daily doses of 480mg and 640mg, respectively). The primary objective of the Phase 1 study was to determine the safety and tolerability of MPC-3100 in cancer patients. The study also included secondary objectives such as characterization of the pharmacokinetic (PK) parameters, determining anti-tumor activity of MPC-3100, and evaluating certain pharmacodynamics (PD) biomarkers.

About the Hsp90 Inhibitor Program

MPC-3100 and its prodrug, MPC-0767, are novel, fully synthetic, orally bioavailable, small molecule inhibitors of heat shock protein 90 (Hsp90). The active inhibitor (MPC-3100) is structurally distinct from geldanamycin- or resorcinol-type Hsp90 inhibitors and this unique structure appears to reduce the off-target toxicities that are common to this group of drugs. In a Phase 1 clinical study, administration of MPC-3100 was shown to be safe and well tolerated and resulted in the in vivo inhibition...
of Hsp90 in cancer patients. The Company plans to initiate a Phase 2 study of MPC-3100 in one or more specific populations of patients with cancer in the second quarter of 2012.

MPC-0767 demonstrates >50-fold increase in solubility compared to MPC-3100 and is converted efficiently into active MPC-3100 following oral administration in animal studies. Based on its solubility, it is expected that MPC-0767 will be easier to formulate into tablets, reducing the overall tablet burden as well as the amount of excipient materials required. The Company expects to submit an IND on MPC-0767 in the first quarter of 2012.

About the Cancer Metabolism Inhibitor Program

MPC-8640 is an orally bioavailable and potent small molecule Cancer Metabolism Inhibitor (CMI) discovered by Myrexis that is currently in preclinical development for the treatment of cancer. MPC-8640 is converted in the body to an active molecule that has been shown to selectively inhibit nicotinamide phosphoribosyltransferase, or Nampt, an enzyme critical for converting nicotinamide into nicotinamide adenine dinucleotide (NAD). Cellular processes such as glucose metabolism, DNA repair and gene expression require and consume NAD. Cancer cells have increased NAD requirements and are highly sensitive to NAD depletion. Blocking the Nampt-NAD pathway severely inhibits cancer cell metabolism, resulting in energy deprivation and ultimately cell death. In animal models, MPC-8640 causes dramatic tumor regressions across multiple tumor types and the Company believes the compound has the potential to be the best-in-class Nampt inhibitor with promise for treating a wide variety of cancers. Myrexis is currently conducting IND enabling studies on MPC-8640.

About Myrexis, Inc.

Myrexis, Inc. is a biotechnology company focused on the development of small molecule therapeutics with novel chemical structures and distinct mechanisms of action. The Company has generated a strong pipeline of differentiated product candidates in oncology and autoimmune diseases. Myrexis is focused on maximizing the therapeutic and commercial value of these molecules by developing potential first-in-class and/or best-in-class treatment options for patients with unmet needs.


Forward Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the attributes, expected development, and potential efficacy of Myrexis' product candidates. These "forward-looking statements" are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by forward-looking statements. These risks and uncertainties include, but are not limited to, the factors discussed under the heading "Risk Factors" contained in Myrexis' Form 10-K, for the year ended June 30, 2011, which was filed with the Securities and Exchange Commission on September 13, 2011, as well as any updates to those risk factors filed from time to time in Myrexis' Quarterly Reports on Form 10-Q or Current Reports on Form 8-K. All information in this press release is as of the date of the release, and Myrexis undertakes no duty to update this information unless required by law.

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