Sole Source

Nerlynx® Breast Cancer Pharmaceutical

MUHC

In accordance with the Collected Rules and Regulations 80.010, MU Health Care (MUHC) requests approval for the sole source purchase of Nerlynx® Breast Cancer Pharmaceutical from Puma Biotechnology, Inc., Los Angeles, California, for an estimated total of $1,875,000 for a three-year term.

Nerlynx® (neratinib) is the first and only FDA-approved kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early stage human epidermal growth factor receptor 2 (HER2)-overexpressed breast cancer, following adjuvant Herceptin® (trastuzumab) based therapy. Approximately 20% to 25% of breast cancer tumors over-express the HER2 protein. HER2-positive breast cancer is often more aggressive than other types of breast cancer, thus increasing the risk of disease progression and death.

Ellis Fischel Cancer Center providers estimate Nerlynx® (neratinib) will be prescribed for approximately 16 patients per year based on current HER2-positive breast cancer diagnoses. This pharmaceutical is an oral tablet taken by patients ongoing for months. Research shows Nerlynx® (neratinib) has shown to decrease the production of the HER2 protein, thus decreasing the cancer progression and chances of death.

Nerlynx® (neratinib) is a limited distribution drug (LDD) not previously available to the Mizzou Specialty Pharmacy. Mizzou Specialty Pharmacy was permitted access to the medication in January 2019 after earning Utilization Review Accreditation Commission (URAC) specialty pharmacy accreditation. Puma Biotechnology, Inc. is the only manufacturer of Nerlynx® (neratinib).

While this specialty pharmaceutical is extremely expensive to purchase, Mizzou Specialty Pharmacy typically receives 33% to 36% operating income through the specialty pharmacy program, which covers the cost of the drug.

The total $1,875,000 expenditure over the three-year term will be paid from the Mizzou Specialty Pharmacy operating funds.

No. 4

Recommended Action – Sole Source – Nerlynx® Breast Cancer Pharmaceutical, MUHC

It was recommended by Chancellor Cartwright, endorsed by President Choi, recommended by the Finance Committee, moved by Curator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and seconded by Curator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, that the following action be approved:

that MUHC be authorized to purchase Nerlynx® Breast Cancer Pharmaceutical from Puma Biotechnology, Inc., Los Angeles, California, at a total cost of $1,875,000 for a three year term.

Funding is as follows:

Mizzou Specialty Pharmacy Operating Fund H0618 733870

Roll call vote Finance Committee YES NO

Curator Brncic

Curator Chatman

Curator Layman

Curator Steelman

The motion .

Roll call vote Full Board: YES NO

Curator Brncic

Curator Chatman

Curator Farmer

Curator Graham

Curator Layman

Curator Phillips

Curator Snowden

Curator Steelman

Curator Sundvold

The motion .