

Puma Biotechnology

3Q -2017 Earnings Call

Commercial Update



November 9, 2017

nerlynx™
(neratinib) tablets



Forward-Looking Safe Harbor Statement

This presentation contains forward-looking statements, including statements regarding the benefits of NERLYNX™ (neratinib) for the extended adjuvant treatment of HER2-positive early stage breast cancer, the potential approval of neratinib for this indication in the European Union and our other drug candidates, commercialization activities, the potential indications of our drug candidates and the development of our drug candidates, including, but not limited to, the anticipated timing for the commencement and completion of various clinical trials and announcement of data relative to these trials. All forward-looking statements included in this presentation involve risks and uncertainties that could cause our actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, which include, but are not limited to, the fact that we have only recently commenced commercialization and shipment of our only FDA approved product, our dependence upon the commercial success of NERLYNX™ (neratinib), our history of operating losses and our expectation that we will continue to incur losses for the foreseeable future, risks and uncertainties related to our ability to achieve or sustain profitability, our ability to predict our future prospects and forecast our financial performance and growth, failure to obtain sufficient capital to fund our operations, the effectiveness of sales and marketing efforts, our ability to obtain FDA approval or other regulatory approvals in the United States or elsewhere for other indications for neratinib or other product candidates, the challenges associated with conducting and enrolling clinical trials, the risk that the results of clinical trials may not support our drug candidate claims, even if approved, the risk that physicians and patients may not accept or use our products, our reliance on third parties to conduct our clinical trials and to formulate and manufacture our drug candidates, risks pertaining to securities class action, derivative and defamation lawsuits, our dependence on licensed intellectual property, and the other risk factors disclosed in our periodic and current reports filed with the Securities and Exchange Commission from time to time, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. We assume no obligation to update these forward-looking statements except as required by law.

U.S. Launch Strategy - executed as planned

PHASE 1: Soft Launch

'Open for Business / Product Shipped'

July 2017

- Commercial infrastructure in place
- Fully staffed headquarters commercial team
- NERLYNX™ shipped to specialty pharmacies
- Reimbursement Hub (Puma Patient Lynx) open
 - Patient Assistance available
 - Co-pay support set up
- Medical Information open
- Prescriptions filled

August

*On-board
and
Train*



PHASE 2: LAUNCH

'Active Promotion'

Sept 2017

- Fully trained salesforce begins calling on health care providers
 - 85 clinical sales specialists
 - 12 nurse educators
 - 20 other roles
- Nurse In-Services
- Compliance and Persistence programs fully operational
 - Texting reminders
 - Pharmacy counseling
- Payer coverage policies in place
- Distribution contracts in place

Key Events - Week of July 17 FDA Approval

U.S. Department of Health and Human Services
U.S. FOOD & DRUG ADMINISTRATION

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Drugs

Home > Drugs > Drug Approvals and Databases > Approved Drugs

Approved Drugs

Hematology/Oncology (Cancer) Approvals & Safety Notifications

Drug Information Soundcast in Clinical Oncology (D.I.S.C.O.)

Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)

FDA approves neratinib for extended adjuvant treatment of early stage HER2-positive breast cancer

On July 17, 2017, the U.S. Food and Drug Administration approved neratinib (NERLYNX, Puma Biotechnology, Inc.) for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.

Approval was based on the ExTeNET trial (NCT00878709), a multicenter, randomized, double-blind, placebo-controlled trial of neratinib following adjuvant trastuzumab treatment. Women (n=2,840) with early-stage HER2-positive breast cancer and within two years of completing adjuvant trastuzumab were randomized to receive either neratinib (n=1,420) or placebo (n=1,420) for one year.

The major efficacy outcome measure was invasive disease-free survival (DFS) defined as the time between the randomization date to the first occurrence of invasive recurrence (local/regional, ipsilateral or contralateral breast cancer), distant recurrence, or death from any cause, within two years and 28 days of follow-up. After two years, DFS was 94.2% in patients treated with neratinib compared with 91.9% in those receiving placebo (HR 0.66; 95% CI: 0.49, 0.90, p=0.008).

The most common adverse reactions (>5%) were diarrhea, nausea, abdominal pain, fatigue, vomiting, rash,

- NERLYNX™ website live
 - Includes prescription form
 - Specialty Pharmacy network listed
- Reimbursement Hub open same day
- Medical Information open same day
- Patient / Physician inquiries same day
- First prescriptions received
- Commercial drug labeled and ready to be shipped to specialty pharmacies

IN EARLY-STAGE HER2+ BREAST CANCER

NERLYNX is your next step to further reduce the risk of recurrence

NEOADJUVANT

SURGERY

RADIATION

ADJUVANT

EXTENDED ADJUVANT

34%
REDUCTION IN RISK OF RECURRENCE VS PLACEBO AT 2 YEARS*

NERLYNX is a kinase inhibitor indicated for the extended adjuvant treatment of adult patients with early-stage HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy.

NOW APPROVED

nerlynx
(neratinib) tablets

* Recurrence is defined as an invasive disease event or death.

Select **IMPORTANT SAFETY INFORMATION**

The most common adverse reactions (AEs) were diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, stomatitis, decreased appetite, muscle spasms, dyspnea, AST or ALT increase, nail discoloration, dry skin, abdominal discomfort, epistaxis, weight decreased, and urinary tract infection.

Please see complete **IMPORTANT SAFETY INFORMATION** on page 14 and accompanying Full Prescribing Information, including Patient Information.

NERLYNX™ Launched to all Oncology Stakeholders



Physicians



Nurses

NOW APPROVED
nerlynx™
(neratinib) tablets



Patients

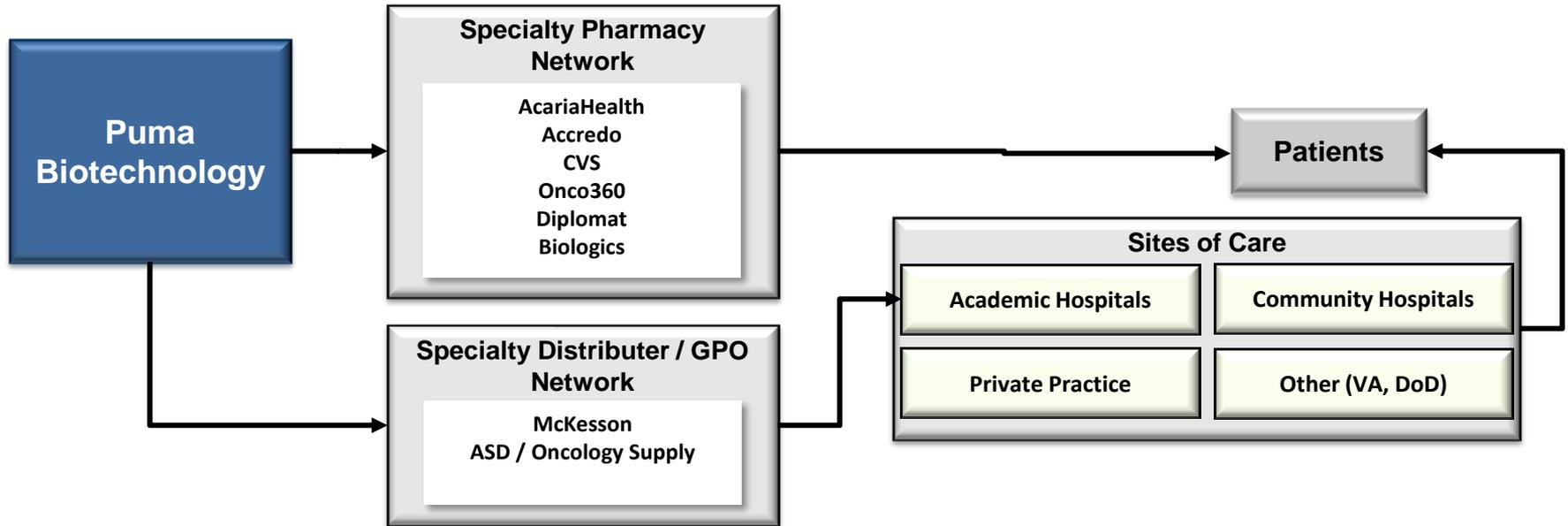


Patient Advocates



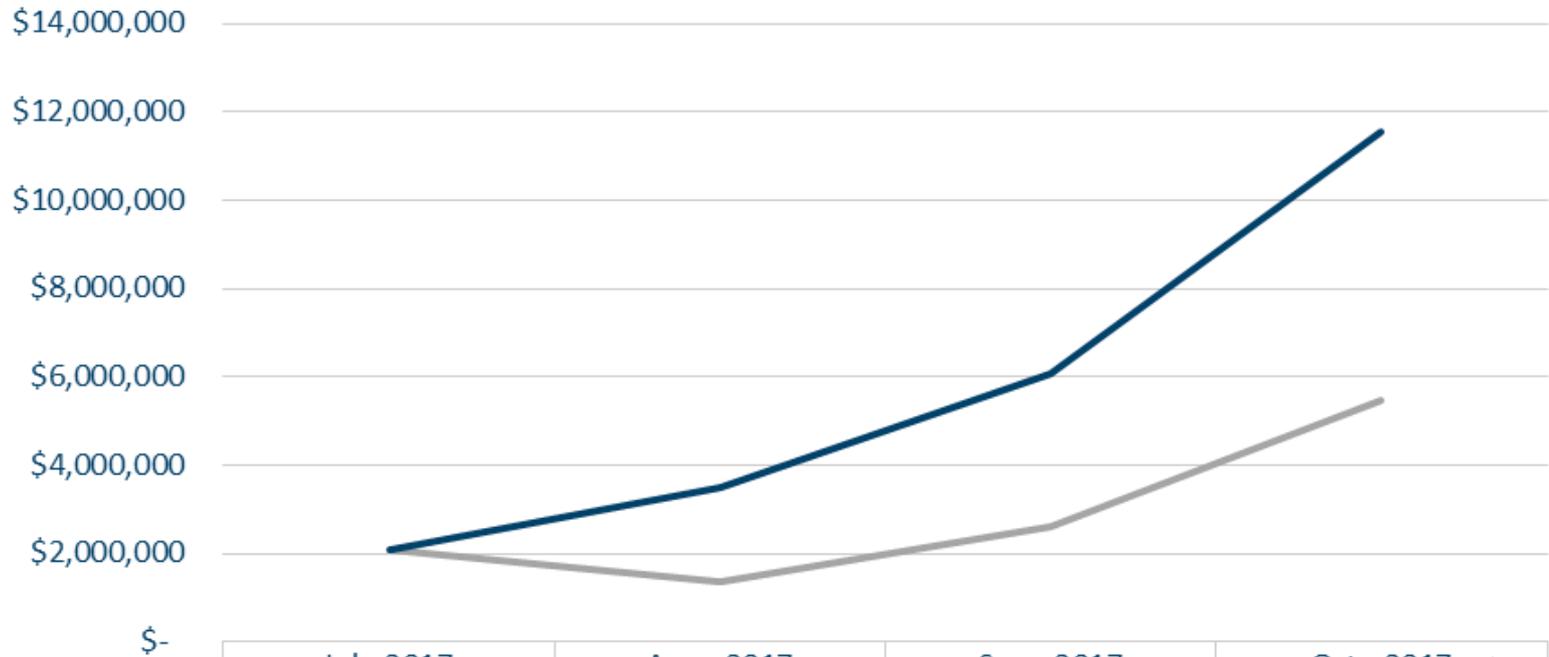
Payers

In addition to our Specialty Pharmacy Network, additional sites of care became available in September



Net Sales since FDA approval is nearly \$ 11.6 Million

Monthly & Cumulative Net Sales



	Jul - 2017	Aug - 2017	Sep - 2017	Oct - 2017 <small>estimate</small>
— Monthly Net	\$2,097,612	\$1,377,402	\$2,601,759	\$5,482,600
— Cumulative Net	\$2,097,612	\$3,475,014	\$6,076,773	\$11,559,372

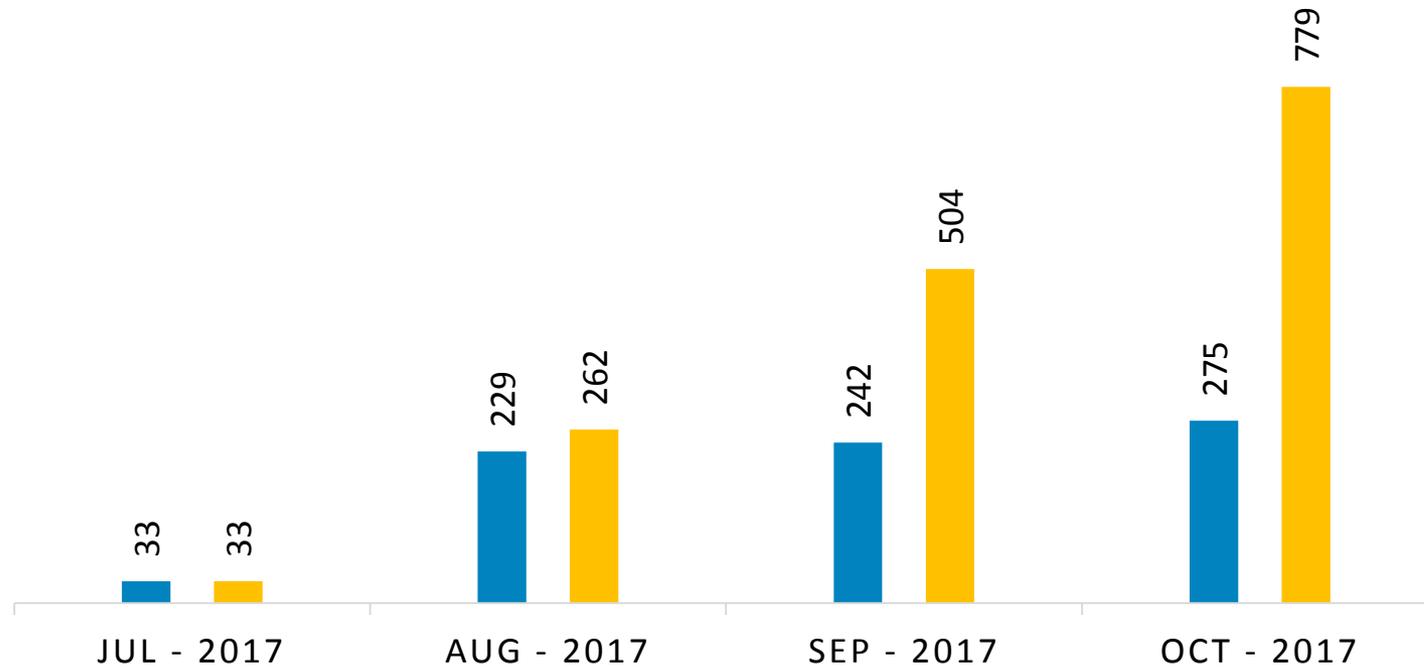
— Monthly Net — Cumulative Net

- July 2017 includes initial stocking by specialty pharmacies

Prescriptions into Specialty Pharmacy Network by Month since FDA Approval

Monthly New & Cumulative Specialty Pharmacy Patients

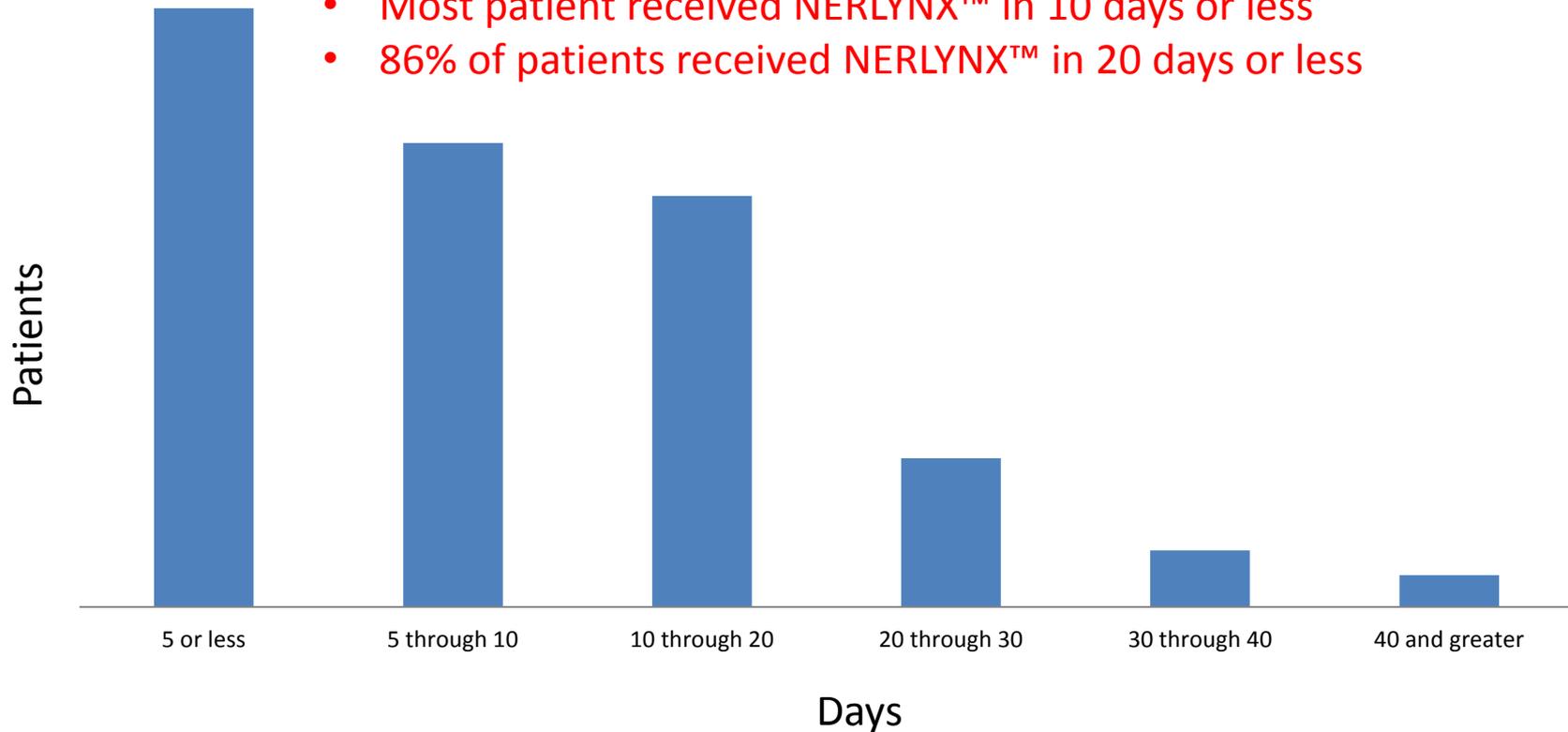
■ SP Patient Enrollments ■ Cumulative SP Patient Enrollments



Average time from Rx received to insurance approval and patient shipment is approximately 10 days

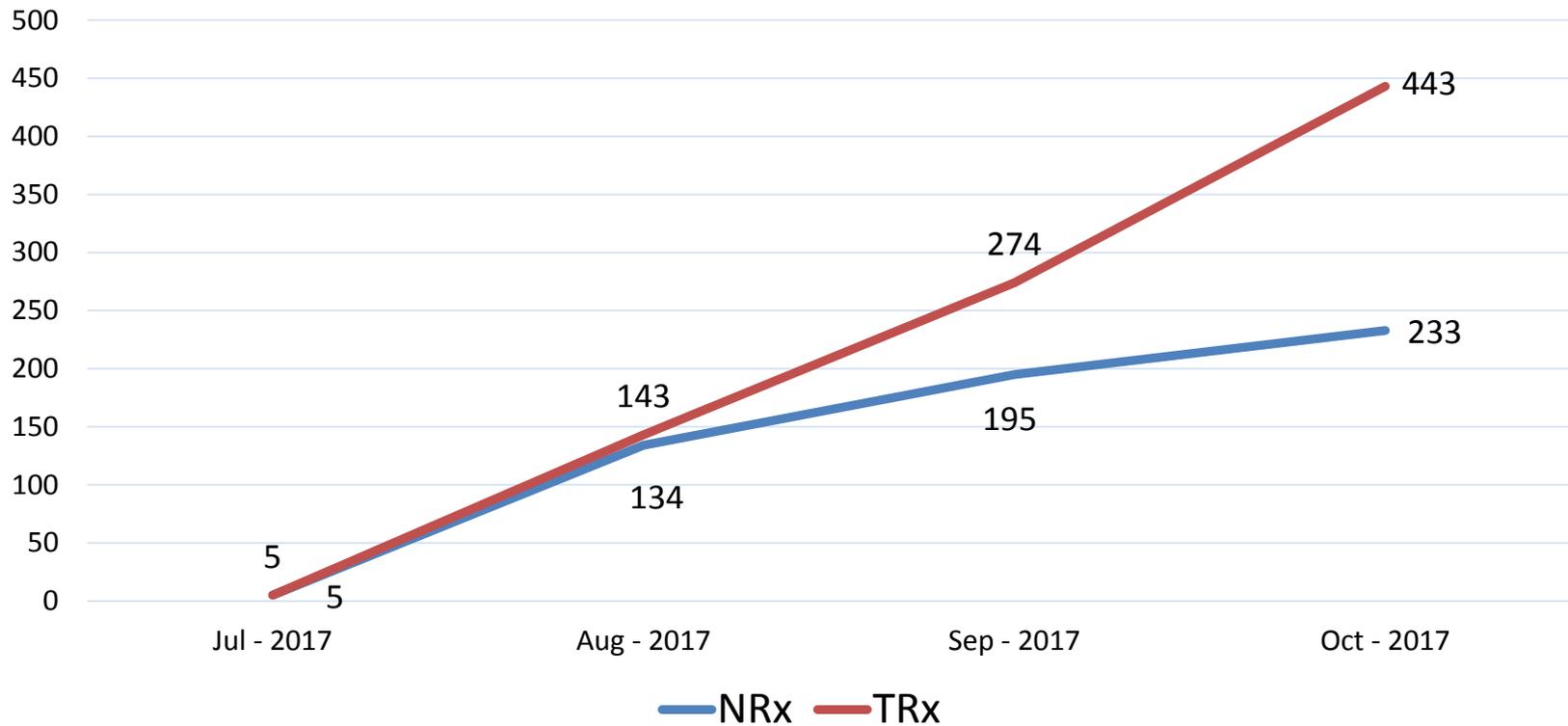
Time to First Patient Dispense by Day Range

- Most patient received NERLYNX™ in 10 days or less
- 86% of patients received NERLYNX™ in 20 days or less



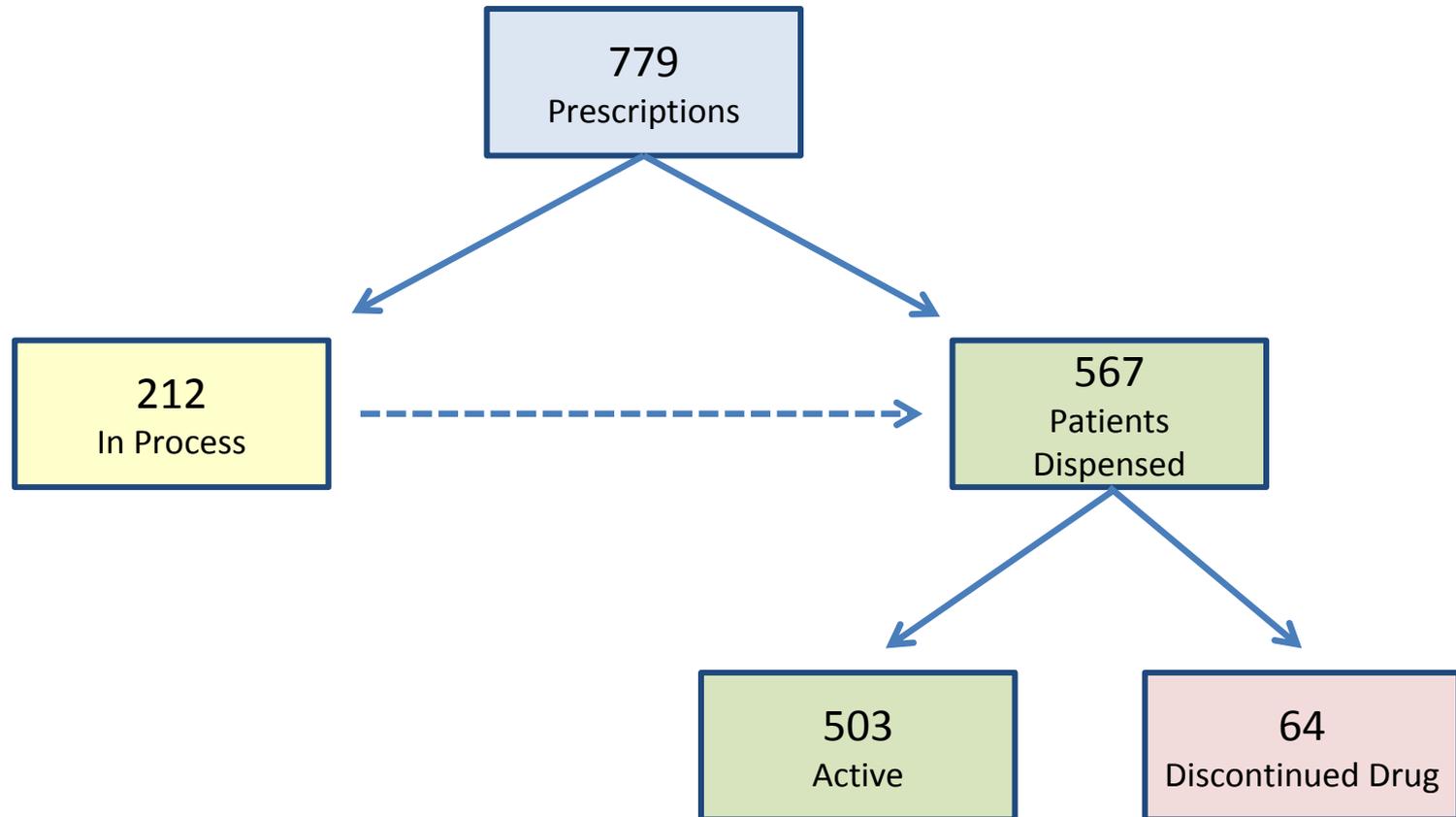
Specialty Pharmacy dispenses to patients by month

Monthly Specialty Pharmacy TRx & NRx



- NRx = New Rx dispended
- TRx = Total Rx dispensed

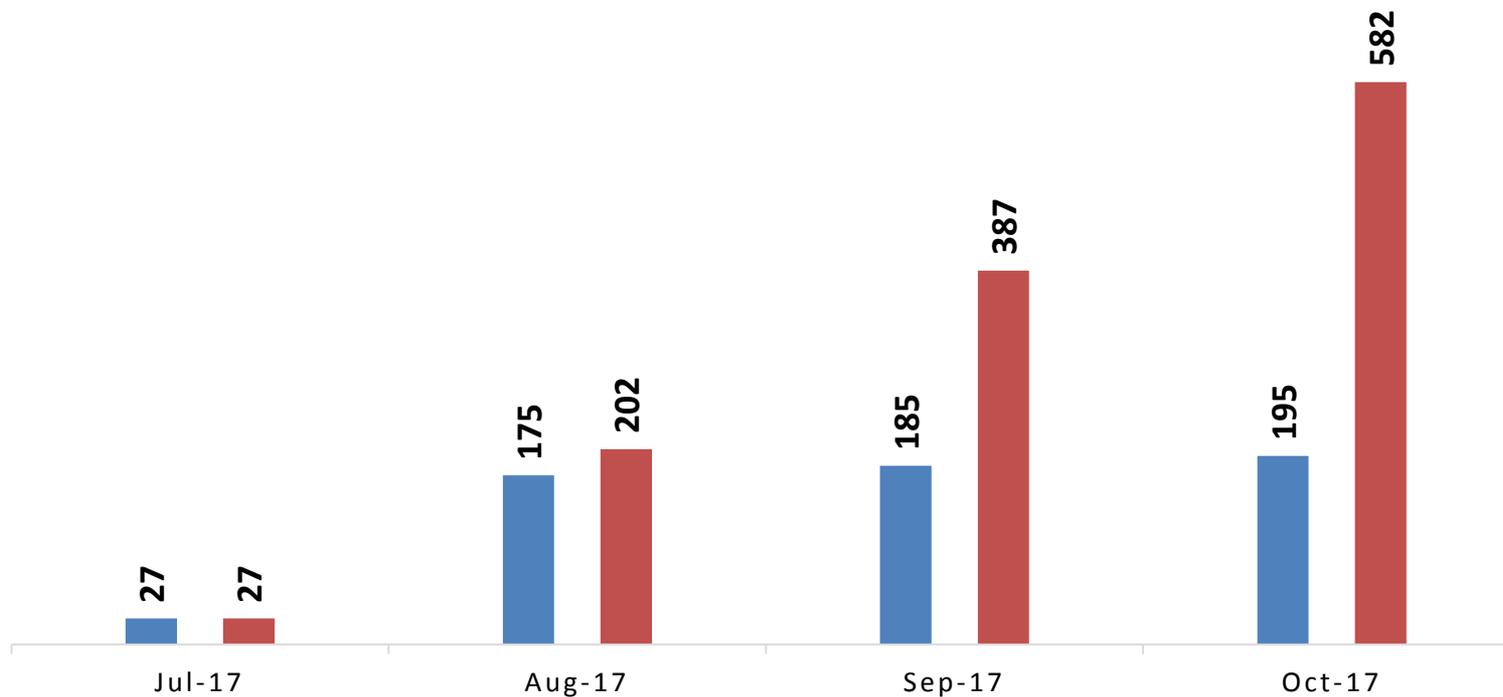
NERLYNX™ Patients in Specialty Pharmacy Network October 31, 2017 Snapshot



New prescribers and Total prescribers

Monthly New & Cumulative NERLYNX Prescribers (Writers)

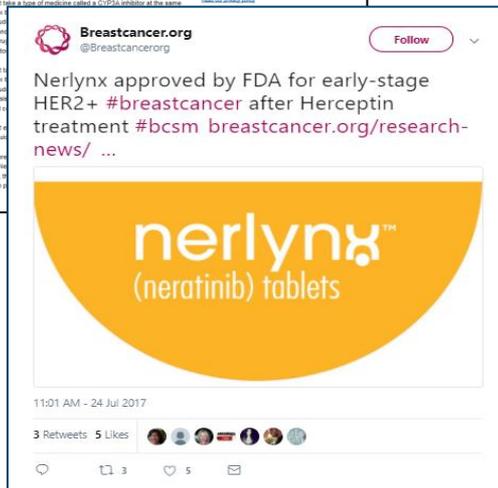
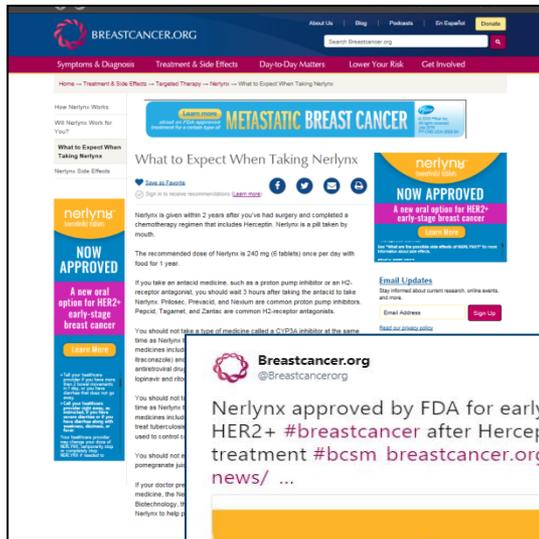
■ New Writers ■ Cumulative Writers



Patient Advocacy support continues to be strong

Cancer Care

Breastcancer.org



Living Beyond Breast Cancer



Positive Payer Coverage of NERLYNX™

Nerlynx (neratinib)

Humana.

Pharmacy Coverage Policy

Effective Date: September 21, 2017
Revision Date: September 21, 2017
Review Date: September 20, 2017
Line of Business: Medicare, Puerto Rico, Commercial
Policy Type: Prior Authorization

Page: 1 of 4

Humana's documents are updated regularly online. When printed, the version of this document becomes uncontrolled. Do not rely on printed copies for the most up-to-date version. Refer to http://apps.humana.com/tad/tad_new/home.aspx to verify that this is the current version before utilizing.

Breast cancer

Initial Therapy:

- The member has early stage (i.e. Stage I, II, III) documented HER2 + positive disease AND
- The member has completed adjuvant therapy with trastuzumab (Herceptin) containing treatment AND
- Nerlynx (neratinib) is being used for the treatment in extended adjuvant setting AND
- The member is taking anti-diarrheal prophylaxis (loperamide) concomitantly during the first two cycles

Continuation of therapy:

- The member is not experiencing any of the following situations:
 - ◊ Grade 4 any adverse event [e.g., diarrhea, ALT (greater than 20 times ULN), bilirubin (greater than 10 times ULN)]
 - ◊ Greater than or equal to grade 2 diarrhea with Nerlynx (neratinib) dosing of 120 mg per day AND
 - If any of the above severe adverse reactions have been experienced, then

- Over 90% covered lives in U.S. have a positive NERLYNX coverage policy like the Humana example
 - The rest are approved case by case
- NERLYNX coverage policies across all payers in the United States cite the label and do not have restrictions to any subgroups
- Positive coverage policies in place despite NCCN guidelines not updated
 - Expect NCCN guidelines by year end 2017