# Utilization and patient characteristics for the trastuzumab originator, biosimilars, and other HER2 inhibitors in the United States

Young Hee Nam,<sup>1</sup> Aaron B. Mendelsohn,<sup>1</sup> James Marshall,<sup>1</sup> Nancy Lin,<sup>2</sup> Jeffrey S. Brown,<sup>1</sup> Cara L. McDermott,<sup>3</sup> Pamala A. Pawloski,<sup>4</sup> Catherine M. Lockhart<sup>3</sup>

<sup>1</sup> Harvard Medical School and Harvard Pilgrim Health Care Institute <sup>2</sup> IQVIA <sup>3</sup> Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) <sup>4</sup> HealthPartners Institute

AMCP Nexus, October 19-22, 2021, Denver, CO.

### **BACKGROUND**

- Biosimilars for trastuzumab, a HER2 inhibitor (HER2I), have been available in the US since 2019
- Information on their utilization and patient characteristics is limited
- We assessed utilization and patient characteristics for the trastuzumab originator, biosimilars, and other HER2Is in the US

**Data**: Healthcare claims for 10/1/2016-up to

from the Biologics and Biosimilars Collective

Intelligence Consortium (BBCIC)'s Distributed

(FDA) Sentinel Common Data Model

2/29/2020 (end date varied across health plans)

Research Network (>95 million persons across 5

**Study population:** Commercially-insured adults

continuously enrolled in their health plan with

medical and drug coverage ≥365 days (baseline

Measurements: Number of incident users and

patients' demographic and clinical characteristics

for each HER2I (trastuzumab, trastuzumab-anns,

Statistical analysis: Descriptive analysis using the

trastuzumab-dkst, trastuzumab/hyaluronidase-

oysk, ado-trastuzumab, lapatinib, neratinib)

Sentinel distributed analysis tools

Peri-Index and "look-forward" variables

"Co-occurring" breast cancer-related treatments

Cardiac tests indicative of LVEF monitoring

Disenrollment or end of ETL

period) prior to their incident HER2I use

Research Partners). Research Partners used curated

data stored in the US Food and Drug Administration

### **METHODS**

- Any secondary neoplasm diagnosis [-365, 0] History of other cancers except basal carcinoma [-365, 0]
- Exclusion Assessment Window Day 0 [0.0]

Inclusion Assessment Window - Day 0 [0, 0]

- Covariate/Confounder Assessment Window Day 0 [0,0] age, sex, race/ethnicity, region
- Covariate/Confounder Assessment Window Comorbidity index (Sentinel standard)

Figure 1. Illustrated study design

Prior HER2-targeted therapies Other breast cancer-related care/management Breast cancer diagnosis, variations by setting of care

Health care utilization metrics (Sentinel standard)

Baseline conditions

- - Number of incident users per person-time decreased with the trastuzumab originator and increased with its biosimilar trastuzumab-anns

Take-away

- Charlson/Elixhauser comorbidity score was the highest for lapatinib and similar between the trastuzumab originator and trastuzumab-anns
- There were variations in patient characteristics between HER2Is and by metastatic status, while the characteristics were generally similar between the trastuzumab originator and trastuzumab-anns

## **RESULTS**

- Number of incident users (incident to any HER2Is): trastuzumab (6,631), trastuzumab-anns (122), ado-trastuzumab emtansine (116), neratinib (54), lapatinib (54), trastuzumab-dkst and trastuzumab/hyaluronidase-oysk (<11)
- Mean age: Highest for trastuzumab/hyaluronidase-oysk (73.7 years; SD, 18.6) and similar between the trastuzumab originator and biosimilars (52.5-59.0)

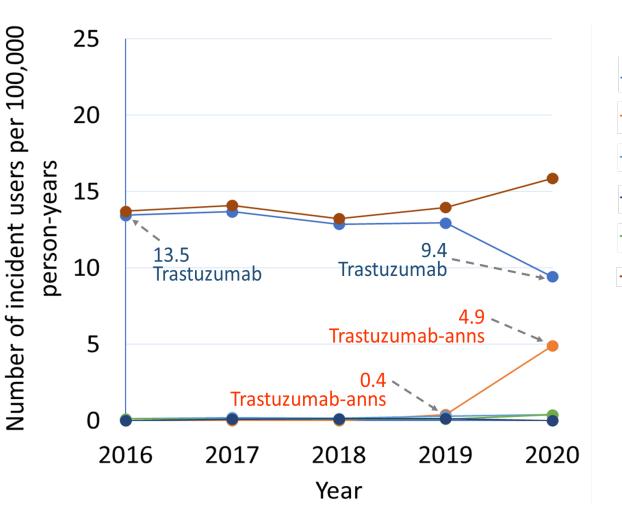
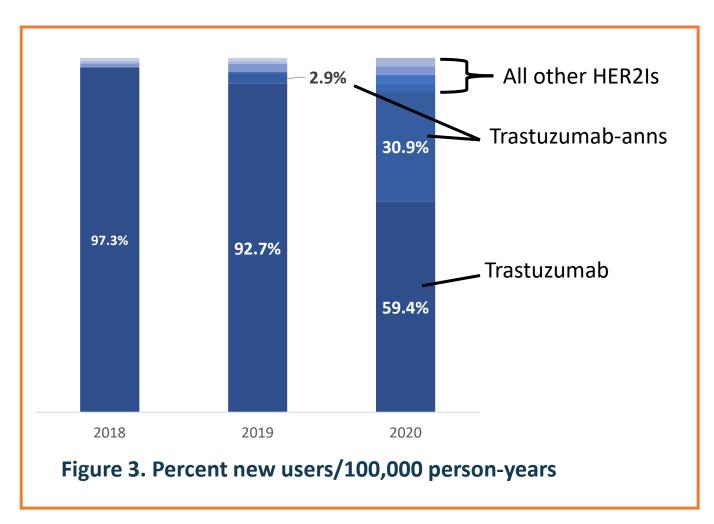


Figure 2. Number of incident users/100,000 person-years

- Trastuzumab
- Trastuzumab-anns
- Ado-trastuzumab emtansine
- Neratinib
- Lapatinib
- Total

Total includes all the 7 HER2Is assessed. Trastuzumabdkst and trastuzumab/hyaluronidase-oysk are not plotted because of their small numbers of incident users (<11 for each)

Note: For 2020, data up to 2/29/21 were analyzed. Data at the beginning of the year may reflect different utilization compared to the rest of the year due to coverage changes.



- Mean number ambulatory health service **encounters** overall was 18.4 (range 13.4 – 22.7) through the study period
- Ambulatory service utilization was higher among patients with metastatic disease (mean 19.8; range 14.0 - 23.7) compared to patients with **non**metastatic disease (mean 16.4; range 11.6 – 20.4)

Table 1. Clinical characteristics of incident users (incident to any HER2Is)					
	Trastuzumab	Trastuzumab-anns	Ado-trastuzumab emtansine	Neratinib	Lapatinib
Charlson/Elixhauser Combined Comorbidity Score	1.1	1.3	1.7	0.5	2.0
Chemotherapy users, % <sup>a</sup>	18.5	14.8	24.1	NC	38.9
Endocrine therapy users, %b	11.1	10.7	41.4	63.0	50.0
Among metastatic breast cancer patients, endocrine therapy users, % <sup>b</sup>	19.3	NC	55.6	NC	69.6

**ACKNOWLEDGMENTS**  This work was supported by the Biologics and Biosimilars Collective Intelligence Consortium (BBCIC), a non-profit, multi-stakeholder collaborative.

 Special thanks to the BBCIC Research Partners: CVS Clinical Trial Services, Anthem/HealthCore, Harvard Pilgrim Health Care, HealthPartners, Kaiser Permanente of Washington.

### DEPARTMENT OF POPULATION MEDICINE











Only part of the characteristics investigated are presented due to limited space. NC: not calculated, for smaller counts (>0, <11). Trastuzumab-dkst and trastuzumab/hyaluronidase-oysk are not shown because of their small numbers of incident users (<11 for each).

<sup>a</sup> Measured during the 183 days prior to the incident HER2I dispensing. <sup>b</sup> Measured during the 365 days prior to the incident HER2I dispensing.

### a. Up to 45 day gaps in medical or pharmacy enrollment allowed

\*Template modified from Schneeweiss et al. Graphical Depiction of Longitudinal Study Designs in Health Care Databases. Ann Intern Med. 2019 Mar 19;170(6):398-406. doi: 10.7326/M18-3079. Epub 2019 Mar 12.