

 Karen MacDonald¹, Ivo Abraham^{1,2,3}, Adolfo Fuentes-Alburo⁴, Henning Austrup⁵, Julia Moebius⁶ ¹Matrix45, Tucson, AZ, USA, ²The University of Arizona College of Pharmacy, Tucson, AZ, USA, ³The University of Arizona Cancer Center, Tucson, AZ, USA ⁴Viatrix, Canonsburg, PA, USA (Former employee), ⁵Meda Pharma GmbH & Co. KG (A Viatrix Company), Bad Homburg, Germany, ⁶Mylan Healthcare GmbH (A Viatrix Company), Hannover, Germany																																																																																																																
Introduction - Costs for cancer treatment have increased worldwide as advanced targeted therapies replace traditional chemotherapies as standard of care in many cancer types. Targeted therapies like trastuzumab have improved the 5-year survival rate in HER2-positive breast cancer even in metastatic disease states. - Biosimilars offer a more affordable option to expensive biological therapies in both supportive and therapeutic cancer care. - Ogivri (Trastuzumab-dkst), a biosimilar trastuzumab, was approved by the FDA in December 2017 and by the EMA in December 2018. - We conducted economic modeling of Ogivri vs Herceptin Hylecta (Trastuzumab SC) in metastatic breast cancer in both the United States (US) and France.	Results - In a panel of 1,000 patients, cost savings of trastuzumab-dkst over trastuzumab-SC monotherapy range from \$564,347 (W3 at 10% conversion) to \$20,706,175 (W1 at 100%) in the US (Table 1) and from \$1,465,126 (W3;10%) to \$25,438,492 (W1;100%) in France (Table 2). - In combination with pertuzumab in a 1,000 patient-panel, trastuzumab-dkst saves up to \$34,234,181 (W1;100%) in the US and up to \$27,601,228 (W1;100%) in France. - In the US, reallocation of these savings can provide between 425 (W3;10%) and 19,810 (W1;100%) additional maintenance doses of trastuzumab-dkst monotherapy, sufficient to treat 8 to 376 patients, respectively, for one year (Table 1). - In France, these savings can provide between 2,606 (W3;10%) and 70,932 (W1;100%) additional maintenance doses or 49 to 1,342 one-year treatment regimens, respectively (Table 2). - For trastuzumab-dkst in combination with pertuzumab, savings in a 1,000 patient-panel could expand access to 202 (W3;10%) to 4,379 (W1;100%) additional maintenance doses or 11 (W3;10%) to 232 (W1;100%) one-year regimens in the US. - In France, savings can provide between 254 (W3;10%) and 4,728 (W1;100%) additional maintenance doses or 13 (W3;10%) to 243 (W1;100%) one-year regimens.	Results Table 1: Cost-savings and budget-neutral expanded access of trastuzumab-dkst in the US <table><tr><th>Cost-savings</th><th>Type of therapy</th><th>Weight 1</th><th>Weight 2</th><th>Weight 3</th></tr><tr><td>Per patient</td><td>Monotherapy</td><td>\$20,706.18</td><td>\$14,647.12</td><td>\$5,643.47</td></tr><tr><td></td><td>Combination</td><td>\$34,234.18</td><td>\$27,646.62</td><td>\$17,642.95</td></tr><tr><td>Panel conversion rate</td><td>10%</td><td>100%</td><td>10%</td><td>100%</td></tr><tr><td>Per panel (1000 patients)</td><td>Monotherapy</td><td>\$2,070,618</td><td>\$20,706,175</td><td>\$14,647,116</td></tr><tr><td></td><td>Combination</td><td>\$5,423,418</td><td>\$34,234,181</td><td>\$27,646,616</td></tr><tr><td>Expanded access</td><td></td><td></td><td></td><td></td></tr><tr><td>Additional maintenance doses</td><td>Monotherapy</td><td>1,980</td><td>19,801</td><td>1,264</td></tr><tr><td></td><td>Combination</td><td>438</td><td>4,379</td><td>343</td></tr><tr><td>Additional 1-yr regimens</td><td>Monotherapy</td><td>38</td><td>376</td><td>24</td></tr><tr><td></td><td>Combination</td><td>23</td><td>232</td><td>18</td></tr></table> Table 2: Cost-savings and budget-neutral expanded access of trastuzumab-dkst in France <table><tr><th>Cost-savings</th><th>Type of therapy</th><th>Weight 1</th><th>Weight 2</th><th>Weight 3</th></tr><tr><td>Per patient</td><td>Monotherapy</td><td>\$25,438.49</td><td>\$20,044.88</td><td>\$14,651.26</td></tr><tr><td></td><td>Combination</td><td>\$27,601.23</td><td>\$22,004.08</td><td>\$16,406.94</td></tr><tr><td>Panel conversion rate</td><td>10%</td><td>100%</td><td>10%</td><td>100%</td></tr><tr><td>Per panel (1000 patients)</td><td>Monotherapy</td><td>\$2,543,849</td><td>\$20,044,879</td><td>\$14,651,265</td></tr><tr><td></td><td>Combination</td><td>\$2,760,123</td><td>\$22,004,081</td><td>\$16,406,935</td></tr><tr><td>Expanded access</td><td></td><td></td><td></td><td></td></tr><tr><td>Additional maintenance doses</td><td>Monotherapy</td><td>7,093</td><td>70,932</td><td>4,354</td></tr><tr><td></td><td>Combination</td><td>473</td><td>4,728</td><td>358</td></tr><tr><td>Additional 1-yr regimens</td><td>Monotherapy</td><td>134</td><td>1,342</td><td>82</td></tr><tr><td></td><td>Combination</td><td>24</td><td>243</td><td>18</td></tr></table>	Cost-savings	Type of therapy	Weight 1	Weight 2	Weight 3	Per patient	Monotherapy	\$20,706.18	\$14,647.12	\$5,643.47		Combination	\$34,234.18	\$27,646.62	\$17,642.95	Panel conversion rate	10%	100%	10%	100%	Per panel (1000 patients)	Monotherapy	\$2,070,618	\$20,706,175	\$14,647,116		Combination	\$5,423,418	\$34,234,181	\$27,646,616	Expanded access					Additional maintenance doses	Monotherapy	1,980	19,801	1,264		Combination	438	4,379	343	Additional 1-yr regimens	Monotherapy	38	376	24		Combination	23	232	18	Cost-savings	Type of therapy	Weight 1	Weight 2	Weight 3	Per patient	Monotherapy	\$25,438.49	\$20,044.88	\$14,651.26		Combination	\$27,601.23	\$22,004.08	\$16,406.94	Panel conversion rate	10%	100%	10%	100%	Per panel (1000 patients)	Monotherapy	\$2,543,849	\$20,044,879	\$14,651,265		Combination	\$2,760,123	\$22,004,081	\$16,406,935	Expanded access					Additional maintenance doses	Monotherapy	7,093	70,932	4,354		Combination	473	4,728	358	Additional 1-yr regimens	Monotherapy	134	1,342	82		Combination	24	243	18
Cost-savings	Type of therapy	Weight 1	Weight 2	Weight 3																																																																																																												
Per patient	Monotherapy	\$20,706.18	\$14,647.12	\$5,643.47																																																																																																												
	Combination	\$34,234.18	\$27,646.62	\$17,642.95																																																																																																												
Panel conversion rate	10%	100%	10%	100%																																																																																																												
Per panel (1000 patients)	Monotherapy	\$2,070,618	\$20,706,175	\$14,647,116																																																																																																												
	Combination	\$5,423,418	\$34,234,181	\$27,646,616																																																																																																												
Expanded access																																																																																																																
Additional maintenance doses	Monotherapy	1,980	19,801	1,264																																																																																																												
	Combination	438	4,379	343																																																																																																												
Additional 1-yr regimens	Monotherapy	38	376	24																																																																																																												
	Combination	23	232	18																																																																																																												
Cost-savings	Type of therapy	Weight 1	Weight 2	Weight 3																																																																																																												
Per patient	Monotherapy	\$25,438.49	\$20,044.88	\$14,651.26																																																																																																												
	Combination	\$27,601.23	\$22,004.08	\$16,406.94																																																																																																												
Panel conversion rate	10%	100%	10%	100%																																																																																																												
Per panel (1000 patients)	Monotherapy	\$2,543,849	\$20,044,879	\$14,651,265																																																																																																												
	Combination	\$2,760,123	\$22,004,081	\$16,406,935																																																																																																												
Expanded access																																																																																																																
Additional maintenance doses	Monotherapy	7,093	70,932	4,354																																																																																																												
	Combination	473	4,728	358																																																																																																												
Additional 1-yr regimens	Monotherapy	134	1,342	82																																																																																																												
	Combination	24	243	18																																																																																																												
Objectives To compare cost-efficiency and budget-neutral expanded access to biosimilar intravenous (IV) trastuzumab-dkst achieved through conversion from subcutaneous (SC) trastuzumab in metastatic breast cancer in US and France.																																																																																																																
Methods The following cost-efficiency models were evaluated: - Trastuzumab-SC (Q3 weeks) vs trastuzumab-dkst IV (weekly) monotherapy - Trastuzumab-SC (Q3 weeks) vs trastuzumab-dkst IV (Q3 weeks) in combination with pertuzumab (and paclitaxel in cycles 1-4) Model inputs included: - A panel of 1000 female patients in three weight (W) categories (US¹: W1: 62.2kg; W2: 73.1kg; W3: 88.6kg; France²: W1: 49.5kg; W2: 66kg; W3: 82.5kg) - Annual cost-savings and expanded access of 1 year treatment with trastuzumab-dkst with conversion rates from 10% to 100% - Drug costs (US: average selling price [US\$]; France: public unit price [€] converted to US purchasing power parity) - Drug administration costs	Discussion The magnitude of per-patient savings in monotherapy is higher in France because: - Costs of trastuzumab-dkst and trastuzumab-SC are both higher in the US, despite purchasing power parity adjustment for France. However, the cost of trastuzumab-SC is 40.5% less in France than in the US, while trastuzumab-dkst is 45.5% lower. This gives trastuzumab-dkst additional advantage over trastuzumab-SC in France. - Drug administration costs are significantly higher in the US than in France. - The US cohort has higher body weight in all 3 weight categories relative to the French cohort. The savings of trastuzumab-dkst in combination with pertuzumab is higher in the US than in France since: - In the US, significant savings associated with drug administration costs are achieved for less frequent (Q3W) dosing. - The cost of pertuzumab in France is higher.	Conclusions - Trastuzumab-dkst monotherapy and in combination with pertuzumab is cost-efficient vs Trastuzumab SC in all 3 patient weights in the US and France. - In a panel of 1,000 patients, cost-savings can be reallocated on a budget-neutral basis to expand access to additional maintenance doses and one-year regimens of trastuzumab-dkst. Acknowledgement and References Acknowledgement - This study was sponsored by Mylan Pharmaceutical Ltd (now Viatrix). Medical writing support was provided by Venkata Satya Sai M and Shanth K from GMW at Viatrix. References - Fryar CD et al. Vital Health Stat 3(46).2021. - World Data. https://www.worlddata.info/average-boyheight.php																																																																																																														