Report Enhertu® - trastuzumab deruxtecan

and they eventually die [1].

Product &	Authorized indications	Essential therapeutic features					NHS impact
Mechanism of action	Licensing status						
Substance:trastuzumabderu	Authorized Indication:	Summary of clinical EFFICACY:					Cost of therapy:
xtecan	EMA:	DESTINY-Breast04 (NCT03734029) was a randomized, two-group, open-label, phase III trial to study the efficacy and safety of trastuzumab deruxtecan in pts with HER2-low*					Considering the ex-factory price
	Trastuzumab deruxtecan as	unresectable or metastatic breast cancer. Eligible pts must have received one or two previous lines of chemotherapy or have had disease recurrence during or within 6					a single administration of
Brand Name:Enhertu	monotherapy is indicated for the	months after completing adjuvant chemotherapy. Pts (of the 494 pts who comprised the hormone receptor-positive cohort) were randomly assigned in a 2:1 ratio to receive					Enhertu® 100mg powder for
	treatment of adults with	trastuzumab deruxtecan (N=331) Q3W at dose of 5.4 mg/Kg or the physician's choice of capecitabine, eribulin, gemcitabine, paclitaxel, or nab-paclitaxel (N=163). The					reconstitution costs 2,344.81 €
Originator/licensee:DaiichiS	unresectable or metastatic HER2-	primary end-point was PFS in the hormone receptor-positive cohort.					[5].
ankyo Europe GmbH	low breast cancer who have	Trastuzumab deruxtecan resulted in significantly longer PFS than the physician's choice of chemotherapy [3].					
· · · · · · · · · · · · · · · · ·	received prior chemotherapy in the			I		٦	Epidemiology:
Classification:NI	metastatic setting or developed		Ad-di DEC	Trastuzumab deruxtecan	Physician's choice chemotherapy	_	In 2020, in Italy, were estimated
• •• • • • • • • • • • • • • • • • • •	disease recurrence during within 6		Median PFS	10.1 months	5.4 months	4	55 thousand new cases of breast
ATC code:L01XC	months of completing adjuvant chemotherapy [1].	*1	HR for disease progression or death	0.51; P<0.001	to attended to the state of		cancer, the most frequent neoplasia. Her2 low breast
OrphanStatus:	chemotherapy [1].	*Low expression of HER2 was defined as a score of 1+ on IHC analysis or as an IHC score of 2+ and negative results on in situ hybridization					cancers represent 55% of al
Eu: No	FDA:	Summary of clinical SA	AFFTV.				breast cancers [6].
Us: No	Trastuzumab deruxtecanis	,		d 98.3% of those in the phys	sician's choice group had at least one	adverse event that emerged or	breast cancers [o].
03. 140	indicated for the treatment of adult	A total of 99.5% of the pts in the trastuzumab deruxtecan group and 98.3% of those in the physician's choice group had at least one adverse event that emerged or worsened after initiation of a trial drug until 47 days after the last dose of the trial drug. The most common drug-related AE of any grade were more frequent in the					
Mechanism of action:	pts with unresectable or metastatic						POSSIBLE PLACE IN THERAPY
Trastuzumab deruxtecan, is	HER2- low (IHC 1+ or IHC 2+/ISH-)		то родения спесов Восер.	Trastuzumab deruxtecan	Physician's choice chemotherap	v	For pts with HR-positive, HER2
made up of two active	breast cancer, as determined by an		SAE	28%	25%	,	negative breast cancer, the
components which are	FDA-approved test, who have		AE of grade ≥3	53%	67%		current standard of care, after
linked together:	received a prior chemotherapy in		AE associated with discontinuation of treatment	16%	8%		exhaustion of hormona
- trastuzumab, is a	the metastatic setting or developed		AE associated with dose reduction	23%	38%		therapies, consists of single-
monoclonal antibody (a	disease recurrence during or within		AE associated with death	4% (14 pts)*	9% (5 pts)**		agent chemotherapies. These
type of protein) that has	6 months of completing adjuvant						agents provide limited benefit in
been designed to attach to	chemotherapy [2].	 	nausea	73%	24%		this setting, with a median PFS of
HER2, which is found in			fatigue	48%	42%		about 3 -5 months in the
large quantities on some	Route of administration: iv	 	alopecia	38%	33%		majority of the studies
cancer cells. By attaching to		The most common drug-related AF of grade 3 or higher					Trastuzumab deruxtecar
HER2, trastuzumab activates	Licensing status		neutropenia	14%	41%		demonstrated a better efficacy
cells of the immune system,	EU CHMP P.O. date:15/12/2022		anemia	8%	5%		and will possibly replace the
which kill the cancer cells.	FDA M.A. date: 4/11/2022		fatigue	8%	5%		single-agent chemotherapies [7].
Trastuzumab also stops	FU Consid Assessed Both control		ILD or pneumonitis drug-related	12%***	1%		
HER2 from stimulating the	EU Speed Approval Pathway: No FDA Speed Approval Pathway: No		Left ventricular dysfunction	5%	0%		OTHER INDICATIONS IN
growth of cancer cells. About a quarter of breast	FDA Speed Approval Pathway: No	<u> </u>	onitis (in 2 pts, 0.5%) and ischemic colitis, disseminated in			8% each):	DEVELOPMENT
cancers overexpress HER2.		**none of them were drug-related					Gastric cancer, Non-small cel
- deruxtecan, is a toxic	ABBREVIATIONS:						lung cancer, Colorectal cancer Uterine cancer, Biliary cancer
substance that kills cells,	AE: adverse event	Ongoing studios:[4]					Oterme cancer, billary cancer
when they attempt to divide	CHMP: Committee for Medicinal Products	Ongoing studies:[4]. For the same indication:Yes					SAME INDICATION IN EARLIEF
and grow. It becomes active	for Human Use HER2: Human Epidermal Growth Factor						LINE(S) OF TREATMENT:
once the trastuzumab	Receptor 2	Tor other maleutions.	C3				yes: trastuzumab and
component has attached to	HR: Hazard Ratio						trastuzumab emtansine
HER2 and enters the cancer	IHC: immunohistochemical		, or the same marganery, no				
cell. Deruxtecan blocks an	ILD: interstitial lung disease	References: [1]. https://www.ema.europa.eu/en/medicines/human/summaries-opinion/enhertu-2					OTHER DRUGS IN
enzyme called	M.A.: Marketing Authorization P: P-value	[2].https://www.accessdata.fda	DEVELOPMENT for the SAM				
topoisomerase I, which is	PFS: progression-free survival	[3]. Modi S, Jacot W, Yamashira T, Sohn J, Vidal M, Tokunaga E, Tsurutani J, Ueno NT, Prat A, Chae YS, Lee KS, Niikura N, Park YH, Xu B, Wang X, Gil-Gil M, Li W, Pierga JY, Im SA, Moore HCF, Rugo NB, Yerushalmin R, Zagouri F, Gombos A, Kim SB, Li Q, Lun Z, Cabricia M, Li W, Pierga JY, Im SA, Moore HCF, Rugo NB, Yerushalmin R, Zagouri F, Gombos A, Kim SB, Li Q, Lun Z, Cabricia M, Li W, Pierga JY, Im SA, Moore HCF, Rugo NB, Yerushalmin R, Zagouri F, Gombos A, Kim SB, Li Q, Lun Z, Cabricia M, Li W, Pierga JY, Im SA, Moore HCF, Rugo NB, Yerushalmin R, Zagouri F, Gombos A, Kim SB, Li Q, Lun Z, Cabricia M, Li W, Pierga JY, Im SA, Moore HCF, Rugo NB, Yerushalmin R, Zagouri F, Gombos A, Kim SB, Li Q, Lun Z, Cabricia M, Li W, Pierga JY, Im SA, Moore HCF, Rugo NB, Yerushalmin R, Zagouri F, Gombos A, Kim SB, Li Q, Lun Z, Li W, Pierga JY, Im SA, Moore HCF, Rugo NB, Yerushalmin R, Zagouri F, Gombos A, Kim SB, Li Q, Lun Z, Li W, Pierga JY, Im SA, Moore HCF, Rugo NB, Yerushalmin R, Zagouri F, Gombos A, Kim SB, Li W, Li W, Pierga JY, Li W, Pie					
involved in copying cell	Pts: patients	Liu Q, Luo T, Saura C, Schmid P, Sun T, Gambhire D, Yung L, Wang Y, Singh J, Vitazka P, Meinhardt G, Harbeck N, Cameron DA; DESTINY-Breast04 Trial Investigators. Trastuzumab Deruxtecan in Previously Treated HER2-Low Advanced Breast Cancer. N Engl J Med. 2022 Jul 7;387(1):9-20. doi: 10.1056/NEJMoa2203690. Epub 2022 Jun 5. PMID: 35665782.					
DNA. By blocking the	Q3W: every 3 weeks	[4]. https://adisinsight.springer.com/drugs/800043383					
enzyme, cancer cells are	SAE: serious adverse event	[5]. https://gallery.farmadati.it/ [6]. https://www.sanita24.ilsole24ore.com/art/medicina-e-ricerca/2022-06-06/tumore-seno-metastatico-her2-low-nuovo-anticorpo-coniugato-riduce-rischio-progressione-malattia-o-morte-50percento-094207.php?uuid=AEKuD0dB *Pos					
prevented from multiplying			wp-content/uploads/2022/01/28897-Trastuzumab-Deruxtecan-For-B				