Δεδομένα ασφάλειας του certolizumab pegol από τα αρχεία της UCB

cut-off date of 31st October 2010

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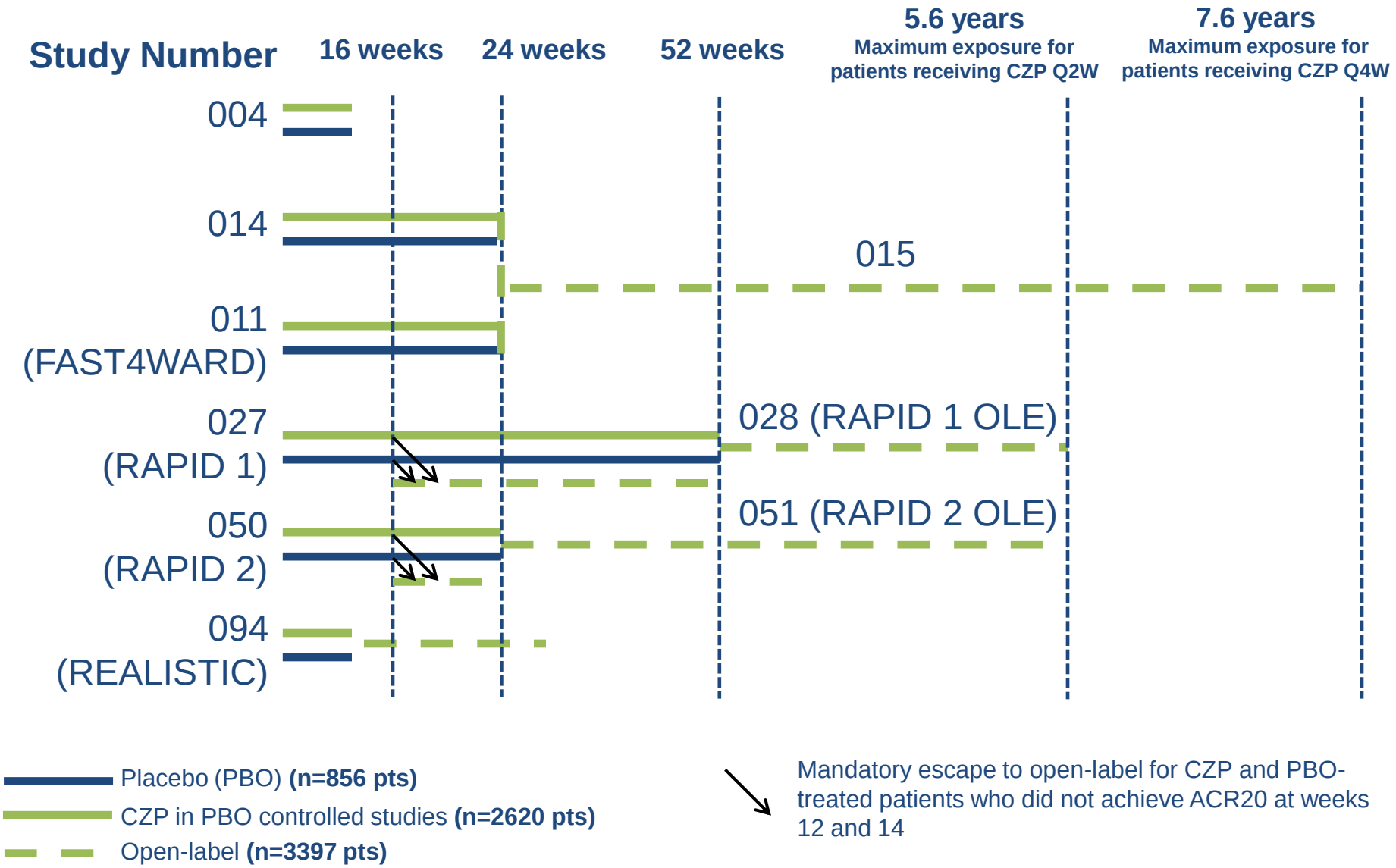
LPSRC approved - APR12/CIMZ17

Δεδομένα ασφάλειας του certolizumab pegol

- Δεδομένα από μελέτες για Ρευματοειδή Αρθρίτιδα μόνο, που έχουν φτάσει τα 5,5 (RAPID) και 7,5 χρόνια (Fast4ward)

- Σύνολο ασθενών N=3.397
- Ολικός χρόνος έκθεσης στο φάρμακο: 8.658 ασθενο-έτη
- όλα τα δοσολογικά σχήματα του φαρμάκου ακόμα και η μη εγκεκριμένη δόση στην Ευρώπη

Exposure to CZP in RA Clinical Studies



Δεδομένα ασφάλειας του certolizumab pegol

Πιο αυστηρός ο ορισμός των Σοβαρών Ανεπιθύμητων Ενεργειών (ΣΑΕ)

Περιλαμβάνει 3 επιπλέον κατηγορίες :

1. Λοιμώξεις που χρειάζονται παρεντερική χορήγηση αντιβιοτικής αγωγής
2. Ανεπιθύμητη Ενέργεια (ΑΕ) που κρίνεται σοβαρή από τον ερευνητή
3. Όλες οι ευκαιριακές λοιμώξεις και οι κακοήθειες

RA: Adverse Events (AEs)

ER – events per 100 pt-yrs; N – number of patients	PBO-Controlled Studies (RCTs)				All Studies (RCTs & OLEs)	
	PBO in all RA PBO-controlled studies		All CZP doses in all RA PBO-controlled studies		All CZP doses in all RA studies (including OLEs)	
	N=856		N=2620		N=3397	
Mean duration of exposure (days)	115.3		159.5		886.4	
Total exposure in pt-yrs	292.3		1197.2		8658.3	
	ER	N	ER	N	ER	N
Any AE	**583.4**	**532**	**575.2**	**1826**	**327.1**	**3026**
Maximum intensity						
Mild	**304.2**	372	**336.3**	1427	**165.4**	2577
Moderate	**220.0**	301	**188.7**	1015	**116.3**	2243
Severe	**39.7**	82	**29.3**	240	**17.7**	806
Serious adverse events	**24.6**	53	**30.0**	244	**21.7**	1016
Withdrawals due to AEs	**10.3**	24	**13.7**	117	**6.8**	482
AEs leading to death	**0.3**	1	**1.1**	10	**0.9**	55

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RA: Most Frequent Adverse Events (AEs) Leading to Withdrawal

ER – events per 100 pt-yrs; *N – number of patients*	PBO-Controlled Studies (RCTs) PBO in all RA PBO-controlled studies N=856	PBO-Controlled Studies (RCTs) All CZP doses in all RA PBO-controlled studies N=2620	All Studies (RCTs & OLEs) All CZP doses in all RA studies (including OLEs) N=3397
Mean duration of exposure (days)	115.3	159.5	886.4
Total exposure (pt-yrs)	292.3	1197.2	8658.3
	ER	**ER**	**ER**
Any AE leading to withdrawal	**10.3**	**13.7**	**6.8**
General disorders and administration site conditions	**0.3**	**1.5**	**0.4**
Infections and infestations	**0.3**	**3.6**	**2.0**
Musculoskeletal and connective tissue disorders	**2.4**	**1.0**	**0.4**
Skin and subcutaneous tissue disorders	**0.7**	**2.3**	**0.7**

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RA: Serious Adverse Events (SAEs)

By MedDRA System Organ Class *ER – events per 100 pt-yrs;* *N – number of patients*	PBO-Controlled Studies (RCTs) PBO in all RA PBO-controlled studies N=856	PBO-Controlled Studies (RCTs) All CZP doses in all RA PBO-controlled studies N=2620	All Studies (RCTs & OLEs) All CZP doses in all RA studies (including OLEs) N=3397
Mean duration of exposure (days)	115.3	159.5	886.4
Total exposure (pt-yrs)	292.3	1197.2	8658.3
	ER	**ER**	**ER**
Any SAE	**24.6**	**30.0**	**21.7**
Blood and lymphatic system disorders	**0.3**	**0.8**	**0.3**
Cardiac disorders	**1.0**	**2.0**	**1.6**
Gastrointestinal disorders	**3.1**	**1.8**	**1.1**
General disorders and administration site conditions	**3.4**	**1.3**	**0.6**
Infections and Infestations	**2.7**	**8.2**	**5.6**
Injury poisoning and procedural complications	**2.4**	**1.8**	**1.8**
Musculoskeletal and connective tissue disorders	**4.5**	**3.3**	**3.4**
Neoplasms benign, malignant and unspecified (including cysts and polyps)	**1.7**	**1.8**	**1.4**
Nervous system disorders	**2.1**	**1.3**	**0.9**
Reproductive system and breast disorders	**0**	**0.8**	**0.5**
Vascular disorders	**0**	**0.9**	**0.7**

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RA: Selected Serious Infections

	PBO-Controlled Studies (RCTs)		All Studies (RCTs & OLEs)
ER – events per 100 pt-yrs; *N – number of patients*	**PBO in all RA PBO-controlled studies N=856**	**All CZP doses in all RA PBO-controlled studies N=2620**	**All CZP doses in all RA studies (including OLEs) N=3397**
Mean duration of exposure (days)	115.3	159.5	886.4
Total exposure in pt-yrs	292.3	1197.2	8658.3
	ER	**ER**	**ER**
Infections and infestations	**2.7**	**8.2**	**5.6**
Tuberculous infections	**0**	**0.8**	**0.6**
Bacterial infections NEC	**0**	**1.1**	**0.6**
Lower respiratory tract and lung infections	**0.7**	**1.3**	**1.3**
Upper respiratory tract infections	**0**	**0.8**	**0.4**

High Level Terms of particular interest were selected and are presented here

Serious infections were recorded as defined by the clinical investigator and were not necessarily bacteriologically confirmed

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NEC = Not Elsewhere Classified

RA: Malignancies

MedDRA System Organ Class High Level Term *ER – events per 100 pt-yrs;* *N – number of patients*	PBO-Controlled Studies (RCTs) PBO in all RA PBO-controlled studies N=856	PBO-Controlled Studies (RCTs) All CZP doses in all RA PBO-controlled studies N=2620	All Studies (RCTs & OLEs) All CZP doses in all RA studies (including OLEs) N=3397
Mean duration of exposure (days)	115.3	159.5	886.4
Total exposure in pt-yrs	292.3	1197.2	8658.3
	ER	ER	ER
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5.1	3.5	3.1
Breast and nipple neoplasms malignant	0	0.1	0.1
Uterine neoplasms malignant NEC	0	0.1	0.03
Diffuse large B-cell lymphomas	0	0	0.01
Extranodal marginal zone B-cell lymphomas (low grade B-cell)	0	0.1	0.01
Hodgkin's disease NEC	0	0	0.01
Non-Hodgkin's lymphomas NEC	0	0	0.01
Mycoses fungoides	0	0	0.01
Bladder neoplasms malignant	0.7	0	0
Colonic neoplasms malignant	0	0.2	0.1
Endocrine neoplasms malignant and unspecified NEC	0.7	0.1	0.1
Hepatobiliary neoplasms malignancy unspecified	0.3	0.2	0.02
Skin melanomas (excl ocular)	0.3	0.1	0.1
Testicular neoplasms malignant	0	0.1	0.02
Skin neoplasms malignant and unspecified (excl melanoma)	0	0.6	0.4

Key malignancies were manually selected from the System Organ Class listing

NEC = Not Elsewhere Classified

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Συμπεράσματα

- Τα νέα δεδομένα ασφάλειας του Cimzia έρχονται σε συμφωνία με αυτά που αναγράφονται στη ΠΧΠ

- Δεν παρατηρήθηκαν νέα safety signals με τη μεγαλύτερη έκθεση στο Cimzia

- Ο τύπος και η συχνότητα εμφάνισης των σοβαρών λοιμώξεων γενικά ήταν παρόμοια με εκείνα που έχουν αναφερθεί με άλλους anti-TNF παράγοντες