

Register of AI Data Exclusivity Granted in Malaysia

For a Second indication of a registered drug product

As described and stipulated in “*Direktif Penguatkuasaan Keperluan Melaksanakan Data Eksklusiviti di Malaysia*” Bil. (11) BPFK/PPP/01/03 Jilid 1, dated 28 February 2011 and effective from 01 March 2011, Data Exclusivity has been granted by the Drug Control Authority, Ministry of Health Malaysia, for the Second indication of a registered product as listed below.

The period of Data Exclusivity is calculated from the date the Second indication is first approved AND granted Data Exclusivity in the country of origin or in any country recognised and deemed appropriate by the Director of Pharmaceutical Services.

No.	Registration (MAL) No.	Product Name	Active Ingredient	Manufacturer	DCA Reference Country for DE			DE Granted by DCA		
					Country	Additional Indication approval date	Exclusivity Expiration	Additional Indication approval date	Protection Period	Exclusivity Expiration
1	MAL20102019AR	Onglyza Tablet 2.5mg	Saxagliptin hydrochloride	Bristol-Myers Squibb Company, USA	USA	16-Dec-11	16-Dec-14	28-Jun-12	3 years	16-Dec-14
2	MAL20102020AR	Onglyza Tablet 5mg	Saxagliptin hydrochloride	Bristol-Myers Squibb Company, USA	USA	16-Dec-11	16-Dec-14	28-Jun-12	3 years	16-Dec-14
3	MAL11115002A	Xarelto 15mg film-coated tablet	Rivaroxaban 15mg	Bayer Pharma AG, Germany	USA	2-Nov-12	2-Nov-15	28-Mar-13	3 years	2-Nov-15
4	MAL11115001A	Xarelto 20mg film-coated tablet	Rivaroxaban 20mg	Bayer Pharma AG, Germany	USA	2-Nov-12	2-Nov-15	28-Mar-13	3 years	2-Nov-15
5	MAL13065048A	Stivarga 40mg Film-coated Tablets	Regorafenib monohydrate 41.49mg (equivalent to 40mg regorafenib)	Bayer Pharma AG, Germany	USA	25-Feb-13	25-Feb-16	23-Jan-14	3 years	25-Feb-16
6	MAL15125055AZ	Jardiance 10mg film coated tablets	Empagliflozin 10 mg	Boehringer Ingelheim Pharma GmbH & CO.KG Germany.	USA	2-Dec-16	2-Dec-19	27-Nov-17	3 years	2-Dec-19

7	MAL15125056AZ	Jardiance 25mg film coated tablets	Empagliflozin 25 mg	Boehringer Ingelheim Pharma GmbH & CO.KG Germany.	USA	2-Dec-16	2-Dec-19	27-Nov-17	3 years	2-Dec-19
8	MAL14075068AZ	Giotrif 20mg film-coated tablets	Afatinib Dimaleate 20mg	Boehringer Ingelheim Pharma GmbH & CO.KG Germany.	USA	15-Apr-16	15-Apr-23	28-Feb-18	3 years	15-Apr-19
9	MAL14075070AZ	Giotrif 30mg film-coated tablets	Afatinib Dimaleate 30mg	Boehringer Ingelheim Pharma GmbH & CO.KG Germany.	USA	15-Apr-16	15-Apr-23	28-Feb-18	3 years	15-Apr-19
10	MAL14075069AZ	Giotrif 40mg film-coated tablets	Afatinib Dimaleate 40mg	Boehringer Ingelheim Pharma GmbH & CO.KG Germany.	USA	15-Apr-16	15-Apr-23	28-Feb-18	3 years	15-Apr-19
11	MAL14075071AZ	Giotrif 50mg film-coated tablets	Afatinib Dimaleate 50mg	Boehringer Ingelheim Pharma GmbH & CO.KG Germany.	USA	15-Apr-16	15-Apr-23	28-Feb-18	3 years	15-Apr-19
12	MAL12095102AZ	Xalkori 200mg Hard Capsules	Crizotinib 200 mg	Pfizer Manufacturing Deutschland GmbH Germany.	USA	11-Mar-16	11-Mar-23	31-May-18	3 years	11-Mar-19
13	MAL12095103AZ	Xalkori 250mg Hard Capsules	Crizotinib 250 mg	Pfizer Manufacturing Deutschland GmbH Germany.	USA	11-Mar-16	11-Mar-23	31-May-18	3 years	11-Mar-19
14	MAL16015076ARZ	Zykadia 150mg Hard Capsules	Ceritinib 150 mg	Novartis Pharma Stein A.G. Switzerland.	USA	26-May-17	26-May-24	28-Aug-18	3 years	26-May-20
15	MAL20172807AZ	Tagrisso Film-Coated Tablet 40mg	Osimertinib 40 mg	AstraZeneca AB, Sweden	USA	18-Apr-18	18-Apr-21	15-Nov-18	3 years	18-Apr-21

16	MAL20172808AZ	Tagrisso Film-Coated Tablet 80mg	Osimertinib 80 mg	AstraZeneca AB, Sweden	USA	18-Apr-18	18-Apr-21	15-Nov-18	3 years	18-Apr-21
17	MAL16065014ACRZ	OFEV Soft Capsules 100 mg	Nintedanib esilate 120.40 mg	Catalent Germany Eberbach GmbH, Germany	USA	06-Sep-2019	06-Sep-2022	03-Sep-2020	3 years	06-Sep-2022
18	MAL16065015ACRZ	OFEV Soft Capsules 150 mg	Nintedanib esilate 180.60 mg	Catalent Germany Eberbach GmbH, Germany	USA	06-Sep-2019	06-Sep-2022	03-Sep-2020	3 years	06-Sep-2022
19	MAL19126002ARZ	Maviret (Glecaprevir 100mg/ Pibrentasvir 40mg) Film Coated Tablets	Glecaprevir 100mg/Pibrentasvir 40mg	Fournier Laboratories Ireland Limited, Ireland	USA	30-Apr-2019	30-Apr-2026	03-Sep-2020	3 years	30-Apr-2022
20	MAL20106001ARZ	RINVOQ® 15mg Extended Release Film Coated Tablets	Upadacitinib Hemihydrate 15.4mg (corresponds to 15 mg of upadacitinib on an anhydrous basis)	Abbvie Ireland NL B.V, Ireland.	EU	25-Jan-2021	18-Dec-2027	08-Oct-2021	3 years	25-Jan-2024
21	MAL15125061ARZ	Entresto 50mg Film - coated Tablets	Sacubitril/Valsartan (corresponds to 50mg LCZ696 free anhydrous acid (sacubitril 24.3mg and valsartan 25.7mg). The API name for Entresto is LCZ696 - ABA in all quality dossier]	Novartis Singapore Pharmaceutical Manufacturing Ptd. Ltd., Singapore	USA	16-Feb-2021	16-Feb-2024	07-Apr-2022	3 years	16-Feb-2024
22	MAL15125062ARZ	Entresto 100mg Film - coated Tablets	Sacubitril/Valsartan (corresponds to 100mg LCZ696 free anhydrous acid (sacubitril 48.6mg and valsartan 51.4mg). The API name for Entresto is LCZ696 - ABA in all quality dossier]	Novartis Singapore Pharmaceutical Manufacturing Ptd. Ltd., Singapore	USA	16-Feb-2021	16-Feb-2024	07-Apr-2022	3 years	16-Feb-2024

23	MAL15125063ARZ	Entresto 200mg Film - coated Tablets	Sacubitril/Valsartan (corresponds to 200mg LCZ696 free anhydrous acid (sacubitril 97.2mg and valsartan 102.8mg). The API name for Entresto is LCZ696 - ABA in all quality dossier]	Novartis Singapore Pharmaceutical Manufacturing Ptd. Ltd., Singapore	USA	16-Feb-2021	16-Feb-2024	07-Apr-2022	3 years	16-Feb-2024
24	MAL20126003AZ	Lorviqua 25 mg Film-Coated Tablets	Lorlatinib 25 mg	Pfizer Manufacturing Deutschland GmbH, Germany	USA	3-Mar-2021	3-Mar-2024	4-Aug-2022	3 years	3-Mar-2024
25	MAL20126004AZ	Lorviqua 100 mg Film-Coated Tablets	Lorlatinib 100 mg	Pfizer Manufacturing Deutschland GmbH, Germany	USA	3-Mar-2021	3-Mar-2024	4-Aug-2022	3 years	3-Mar-2024
26	MAL25036129ARZ	Fabhalta 200mg Hard Capsules	Iptacopan 200 mg	Novartis Pharma Produktions GmbH, Germany	USA	20-Mar-2025	20-Mar-2028	7-May-2026	3 years	20-Mar-2028
27	MAL24046010AZ	Firialta Film Coated Tablet 10mg	Finerenone micronised 10 mg	Bayer AG, Germany	USA	11-Jul-2025	11-Jul-2028	7-May-2026	3 years	11-Jul-2028
28	MAL24046011AZ	Firialta Film Coated Tablet 20mg	Finerenone micronized 20mg	Bayer AG, Germany	USA	11-Jul-2025	11-Jul-2028	7-May-2026	3 years	11-Jul-2028
29	MAL24126007AZ	Pluvicto 1000 MBq/mL Solution for Injection/	Lutetium (177Lu) vipivotide tetraxetan 1000 MBq/mL	Advanced Accelerator Applications S.R.L., Italy	USA	28-Mar-2025	28-Mar-2028	8-Jun-2026	3 years	28-Mar-2028

DCA: Drug Control Authority; DE: Data Exclusivity