

Register of Data Exclusivity Granted in Malaysia

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 New Drug Products containing New Chemical Entities as listed below.

The period of Data Exclusivity is calculated from the date the product is first registered or granted marketing authorisation 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 | Registration Date | Exclusivity Expiration | Registration Date | Protection Period | Exclusivity Expiration |
| 1 | MAL12015017A | Gilenya 0.5mg Hard Capsule | Fingolimod Hydrochloride | Novartis Pharma Stein AG, Switzerland | USA | 21-Sep-10 | 21-Sep-15 | 19-Jan-12 | 5 years | 21-Sep-15 |
| 2 | MAL12035083AR | Victrelis 200mg Hard Capsules | Boceprevir | Schering-Plough (Singapore) Pte. Ltd., Singapore | USA | 13-May-11 | 13-May-16 | 29-Mar-12 | 5 years | 13-May-16 |
| 3 | MAL12095101A | Halaven 0.44mg/ml Solution for Injection | Eribulin mesylate | Nerviano Medical Sciences S.r.l., Italy | USA | 15-Nov-10 | 15-Nov-15 | 27-Sept-12 | 5 years | 15-Nov-15 |
| 4 | MAL12095102A | Xalkori 200mg Hard Capsules | Crizotinib | Pfizer Manufacturing Deutschland GmbH Germany | USA | 26-Aug-11 | 26-Aug-16 | 27-Sept-12 | 5 years | 26-Aug-16 |
| 5 | MAL12095103A | Xalkori 250mg Hard Capsules | Crizotinib | Pfizer Manufacturing Deutschland GmbH Germany | USA | 26-Aug-11 | 26-Aug-16 | 27-Sept-12 | 5 years | 26-Aug-16 |
| 6 | MAL12115076AC | Zinforo 600mg powder for concentrate for solution for infusion | Ceftaroline fosamil | ACS Dobfar S.p.A., Italy | USA | 29-Oct-10 | 29-Oct-15 | 29-Nov-12 | 5 years | 29-Oct-15 |

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|----|--------------|--------------------------------------|--|--|-----|-------------|-------------|-------------|---------|-------------|
| 7 | MAL13025059A | Jakavi 5mg Tablet | Ruxolitinib phosphate 6.60mg (corresponds to 5mg ruxolitinib free base) | Novartis Pharma Stein AG, Switzerland | USA | 16-Nov-11 | 16-Nov-16 | 28-Feb-13 | 5 years | 16-Nov-16 |
| 8 | MAL13025060A | Jakavi 15mg Tablet | Ruxolitinib phosphate 19.80mg (corresponds to 15mg ruxolitinib free base) | Novartis Pharma Stein AG, Switzerland | USA | 16-Nov-11 | 16-Nov-16 | 28-Feb-13 | 5 years | 16-Nov-16 |
| 9 | MAL13025061A | Jakavi 20mg Tablet | Ruxolitinib phosphate 26.40mg (corresponds to 20mg ruxolitinib free base) | Novartis Pharma Stein AG, Switzerland | USA | 16-Nov-11 | 16-Nov-16 | 28-Feb-13 | 5 years | 16-Nov-16 |
| 10 | MAL13065048A | Stivarga 40mg Film-coated Tablets | Regorafenib monohydrate 41.49mg (equivalent to 40mg regorafenib) | Bayer Pharma AG, Germany | USA | 27-Sept-12 | 27-Sept-17 | 27-June-13 | 5 years | 27-Sept-17 |
| 11 | MAL13115126A | Inlyta Film-coated Tablets 1mg | Axitinib 1mg | Pfizer Manufacturing Deutschland GmbH, Germany | USA | 27-Jan-12 | 27-Jan-17 | 6-Nov-13 | 5 years | 27-Jan-17 |
| 12 | MAL13115127A | Inlyta Film-coated Tablets 5mg | Axitinib 5mg | Pfizer Manufacturing Deutschland GmbH, Germany | USA | 27-Jan-12 | 27-Jan-17 | 6-Nov-13 | 5 years | 27-Jan-17 |
| 13 | MAL14015013A | Forxiga 5mg Film- Coated Tablet | Dapagliflozin Propanediol 6.150mg (equivalent to dapagliflozin 5mg) | Bristol-Myers Squibb Company, US | EU | 12-Nov-2012 | 12-Nov-2017 | 23-Jan-2014 | 5 years | 12-Nov-2017 |
| 14 | MAL14015014A | Forxiga 10mg Film- Coated Tablet | Dapagliflozin Propanediol 12.30mg (equivalent to dapagliflozin 10mg) | Bristol-Myers Squibb Company, US | EU | 12-Nov-2012 | 12-Nov-2017 | 23-Jan-2014 | 5 years | 12-Nov-2017 |

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|----|---------------|---|--|---|-----|-----------------|-----------------|--------------------|---------|-----------------|
| 15 | MAL14035002A | Fycompa 2mg film-coated tablets | Perampanel 2.1mg (Anhydrous basis 2mg) | Eisai Manufacturing Limited, UK | EU | 23-July-2012 | 23-July-2017 | 27-March-2014 | 5 years | 23-July-2017 |
| 16 | MAL14035005A | Fycompa 4mg film-coated tablets | Perampanel 4.2mg (Anhydrous basis 4mg) | Eisai Manufacturing Limited, UK | EU | 23-July-2012 | 23-July-2017 | 27-March-2014 | 5 years | 23-July-2017 |
| 17 | MAL14035003A | Fycompa 6mg film-coated tablets | Perampanel 6.2mg (Anhydrous basis 6mg) | Eisai Manufacturing Limited, UK | EU | 23-July-2012 | 23-July-2017 | 27-March-2014 | 5 years | 23-July-2017 |
| 18 | MAL14035001A | Fycompa 8mg film-coated tablets | Perampanel 8.3mg (Anhydrous basis 8mg) | Eisai Manufacturing Limited, UK | EU | 23-July-2012 | 23-July-2017 | 27-March-2014 | 5 years | 23-July-2017 |
| 19 | MAL14035004A | Fycompa 10mg film-coated tablets | Perampanel 10.4mg (Anhydrous basis 10mg) | Eisai Manufacturing Limited, UK | EU | 23-July-2012 | 23-July-2017 | 27-March-2014 | 5 years | 23-July-2017 |
| 20 | MAL14035006A | Fycompa 12mg film-coated tablets | Perampanel 12.5mg (Anhydrous basis 12mg) | Eisai Manufacturing Limited, UK | EU | 23-July-2012 | 23-July-2017 | 27-March-2014 | 5 years | 23-July-2017 |
| 21 | MAL14055146AC | Xofigo (Radium-223 Dichloride) 1000 kBq/mL Solution for Injection | Radium-223 Dichloride 6000kBq/6mL | Institute for Energy Technology, Kjeller, Norway. | USA | 15-May-2013 | 15-May-2018 | 9-May-2014 | 5 years | 15-May-2018 |
| 22 | MAL14075067A | Xeljanz Film-Coated Tablets 5mg | Tofacitinib citrate 8.078mg, equivalent to 5mg tofacitinib | Pfizer Manufacturing Deutschland GmbH, Germany | USA | 6-November-2012 | 6-November-2017 | 24-July -2014 | 5 years | 6-November-2017 |
| 23 | MAL14115019AR | Adempas 0.5 mg Film Coated Tablet | Riociguat 0.5mg | Bayer Pharma AG, Germany | USA | 8-October-2013 | 8-October-2018 | 24-November - 2014 | 5 years | 8-October-2018 |
| 24 | MAL14115022AR | Adempas 1.0mg Film Coated Tablet | Riociguat 1.0mg | Bayer Pharma AG, Germany | USA | 8-October-2013 | 8-October-2018 | 24-November - 2014 | 5 years | 8-October-2018 |

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|----|----------------|---|---|-----------------------------|-----|-----------------------|-----------------------|-----------------------|---------|-----------------------|
| 25 | MAL14115020AR | Adempas 1.5 mg Film Coated Tablet | Riociguat 1.5mg | Bayer Pharma AG, Germany | USA | 8-October-2013 | 8-October-2018 | 24-November - 2014 | 5 years | 8-October-2018 |
| 26 | MAL14115023AR | Adempas 2.0 mg Film Coated Tablet | Riociguat 2.0mg | Bayer Pharma AG, Germany | USA | 8-October-2013 | 8-October-2018 | 24-November - 2014 | 5 years | 8-October-2018 |
| 27 | MAL14115021AR | Adempas 2.5 mg Film Coated Tablet | Riociguat 2.5mg | Bayer Pharma AG, Germany | USA | 8-October-2013 | 8-October-2018 | 24-November - 2014 | 5 years | 8-October-2018 |
| 28 | MAL15045161A | Brintellix 5mg Film- coated Tablets | Vortioxetine hydrobromide 6.355mg (equivalent to 5mg vortioxetine) | H.Lundbeck A/S, Denmark | USA | 30-September- 2013 | 30-September- 2018 | 30-April-2015 | 5 years | 30-September- 2018 |
| 29 | MAL15045160A | Brintellix 10mg Film-coated Tablets | Vortioxetine hydrobromide 12.710mg (equivalent to 10mg vortioxetine) | H.Lundbeck A/S, Denmark | USA | 30-September- 2013 | 30-September- 2018 | 30-April-2015 | 5 years | 30-September- 2018 |
| 30 | MAL15045162A | Brintellix 15mg Film-coated Tablets | Vortioxetine hydrobromide 19.065mg (equivalent to 15mg vortioxetine) | H.Lundbeck A/S, Denmark | USA | 30-September- 2013 | 30-September- 2018 | 30-April-2015 | 5 years | 30-September- 2018 |
| 31 | MAL15045163A | Brintellix 20mg Film-coated Tablets | Vortioxetine hydrobromide 25.420mg (equivalent to 20mg vortioxetine) | H.Lundbeck A/S, Denmark | USA | 30-September- 2013 | 30-September- 2018 | 30-April-2015 | 5 years | 30-September- 2018 |
| 32 | MAL15085076ACR | Tecfidera 120 mg gastro-resistant hard capsules | Dimethyl fumarate 120 mg | Vifor SA, Switzerland | USA | 27-March-2013 | 27-March-2018 | 20-August-2015 | 5 years | 27-March-2018 |

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|----|----------------|---|--|--|-----------|-----------------|-----------------|-------------------|---------|-----------------|
| 33 | MAL15085078ACR | Tecfidera 240 mg gastro-resistant hard capsules | Dimethyl fumarate 240 mg | Vifor SA, Switzerland | USA | 27-March-2013 | 27-March-2018 | 20-August-2015 | 5 years | 27-March-2018 |
| 34 | MAL15095034A | Sovaldi 400mg Film-Coated Tablets | Sofosbuvir 400mg | Gilead Sciences Ireland UC, Ireland | USA | 6-December-2013 | 6-December-2018 | 28-September-2015 | 5 years | 6-December-2018 |
| 35 | MAL15125055A | Jardiance 10mg Film-Coated Tablets | Empagliflozin 10mg | Boehringer Ingelheim Pharma GmbH & Co. KG, Germany | Australia | 30-April-2014 | 30-April-2019 | 22-December-2015 | 5 years | 30-April-2019 |
| 36 | MAL15125056A | Jardiance 25mg Film-Coated Tablets | Empagliflozin 25mg | Boehringer Ingelheim Pharma GmbH & Co. KG, Germany | Australia | 30-April-2014 | 30-April-2019 | 22-December-2015 | 5 years | 30-April-2019 |
| 37 | MAL15125061AR | Entresto 50mg Film-coated Tablets | Sacubitril/valsartan 56.551mg [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 Pharma Stein AG, Switzerland | USA | 7-July-2015 | 7-July-2020 | 22-December-2015 | 5 years | 7-July-2020 |
| 38 | MAL15125062AR | Entresto 100mg Film-coated Tablets | Sacubitril/valsartan 113.103mg [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 Pharma Stein AG, Switzerland | USA | 7-July-2015 | 7-July-2020 | 22-December-2015 | 5 years | 7-July-2020 |

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| 39 | MAL15125063AR | Entresto 200mg Film-coated Tablets | Sacubitril/valsartan 226.206mg [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 Pharma Stein AG, Switzerland | USA | 7-July-2015 | 7-July-2020 | 22-December- 2015 | 5 years | 7-July-2020 |
| 40 | MAL16015076AR | Zykadia 150mg Hard Capsules | Ceritinib 150mg | Novartis Pharma Stein AG, Switzerland | USA | 29-April-2014 | 29-April-2019 | 21-January-2016 | 5 years | 29-April-2019 |
| 41 | MAL16065014ACRZ | OFEV Soft Capsules 100 mg | Nintedanib esilate 120.40mg equivalent to 100 mg of nintedanib as free base | Catalent Germany Eberbach GmbH, Germany | USA | 15-October-2014 | 15-October-2019 | 7-June-2016 | 5 years | 15-October-2019 |
| 42 | MAL16065015ACRZ | OFEV Soft Capsules 150 mg | Nintedanib esilate 180.60mg equivalent to 150 mg of nintedanib as free base | Catalent Germany Eberbach GmbH, Germany | USA | 15-October-2014 | 15-October-2019 | 7-June-2016 | 5 years | 15-October-2019 |
| 43 | MAL16065029ACRZ | Opsumit 10mg Film-Coated Tablets | Macitentan 10mg | Patheon Italia S.P.A., Italy | USA | 18-October-2013 | 18-October-2018 | 7-June-2016 | 5 years | 18-October-2018 |
| 44 | MAL16065002ARZ | Ibrance Capsules 75mg | Palbociclib 75mg | Pfizer Manufacturing Deutschland GmbH, Germany | USA | 3-February-2015 | 3-February-2020 | 7-June-2016 | 5 years | 3-February-2020 |
| 45 | MAL16065003ARZ | Ibrance Capsules 100mg | Palbociclib 100mg | Pfizer Manufacturing Deutschland GmbH, Germany | USA | 3-February-2015 | 3-February-2020 | 7-June-2016 | 5 years | 3-February-2020 |
| 46 | MAL16065004ARZ | Ibrance Capsules 125mg | Palbociclib 125mg | Pfizer Manufacturing Deutschland GmbH, Germany | USA | 3-February-2015 | 3-February-2020 | 7-June-2016 | 5 years | 3-February-2020 |

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| 47 | MAL16065041ACRZ | Lynparza 50mg Hard Capsules | Olaparib 50mg | Patheon Pharmaceuticals Inc., United States | EU | 16-December-2014 | 16-December-2019 | 30-June-2016 | 5 years | 16-December-2019 |
| 48 | MAL16125024ACRZ | Zerbaxa 1.5g powder for solution for injection | *Ceftolozane sulphate [product contains ceftolozane sulphate and tazobactam sodium] *DE for new active ingredient | Steri-Pharm, LLC, United States | USA | 19-December-2014 | 19-December-2019 | 22-December-2016 | 5 years | 19-December-2019 |
| 49. | MAL20172807AZ | Tagrisso Film-Coated Tablet 40mg | Osimertinib mesylate 47.7mg (equivalent to 40mg osimertinib) | AstraZeneca AB, Sweden | USA | 13-November-2015 | 13-November-2020 | 28-April-2017 | 5 years | 13-November-2020 |
| 50. | MAL20172808AZ | Tagrisso Film-Coated Tablet 80mg | Osimertinib mesylate 95.4mg (equivalent to 80mg osimertinib) | AstraZeneca AB, Sweden | USA | 13-November-2015 | 13-November-2020 | 28-April-2017 | 5 years | 13-November-2020 |
| 51. | MAL17025019ARZ | Farydak 10mg Hard Capsules | Panobinostat lactate anhydrous 12.576mg (Corresponding to 10.000 mg of panobinostat) | Novartis Farmaceutica S.A., Spain. | USA | 23-February-2015 | 24-February-2020 | 24-February-2017 | 5 years | 24-February-2020 |
| 52. | MAL17025020ARZ | Farydak 15mg Hard Capsules | Panobinostat lactate anhydrous 18.864mg (Corresponding to 15.000 mg of panobinostat) | Novartis Farmaceutica S.A., Spain. | USA | 23-February-2015 | 24-February-2020 | 24-February-2017 | 5 years | 24-February-2020 |
| 53. | MAL17025021ARZ | Farydak 20mg Hard Capsules | Panobinostat lactate anhydrous 25.152mg (Corresponding to 20.000 mg of panobinostat) | Novartis Farmaceutica S.A., Spain. | USA | 23-February-2015 | 24-February-2020 | 24-February-2017 | 5 years | 24-February-2020 |

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| 54. | MAL17107002ACZ | Duaklir Genuair 340/12 mcg Inhalation Powder | Acidinium bromide 400 mcg (the delivered dose is 396 mcg of acidinium bromide equivalent to 340 mcg of acidinium) and formoterol fumarate dihydrate 12 mcg (the delivered dose is 11.8 mcg formoterol fumarate dihydrate) | Industrias Farmaceuticas Almirall, Spain. | EU | 19-November-2014 | 19-November-2022 | 3-October-2017 | 5 years | 19-November-2019 |
| 55. | MAL18046001ARZ | Kryxana 200mg Film-coated Tablets | Ribociclib succinate 254.4mg (equivalent to 200mg of ribociclib free base). | Novartis Singapore Pharmaceutical Manufacturing Ptd. Ltd. | USA | 13 March 2017 | 13 March 2022 | 2 April 2018 | 5 years | 13 March 2022 |
| 56. | MAL18086114ACRZ | Upravi 200 Microgram Film-Coated Tablets | Selexipag 200mcg | Excella Gmbh, Germany | USA | 21 December 2015 | 21 December 2020 | 28 August 2018 | 5 years | 21 December 2020 |
| 57. | MAL18086113ACRZ | Upravi 400 Microgram Film-Coated Tablets | Selexipag 400mcg | Excella Gmbh, Germany | USA | 21 December 2015 | 21 December 2020 | 28 August 2018 | 5 years | 21 December 2020 |
| 58. | MAL18086112ACRZ | Upravi 600 Microgram Film-Coated Tablets | Selexipag 600mcg | Excella Gmbh, Germany | USA | 21 December 2015 | 21 December 2020 | 28 August 2018 | 5 years | 21 December 2020 |
| 59. | MAL18086111ACRZ | Upravi 800 Microgram Film-Coated Tablets | Selexipag 800mcg | Excella Gmbh, Germany | USA | 21 December 2015 | 21 December 2020 | 28 August 2018 | 5 years | 21 December 2020 |
| 60. | MAL18086110ACRZ | Upravi 1000 Microgram Film-Coated Tablets | Selexipag 1000mcg | Excella Gmbh, Germany | USA | 21 December 2015 | 21 December 2020 | 28 August 2018 | 5 years | 21 December 2020 |
| 61. | MAL18086109ACRZ | Upravi 1200 Microgram Film-Coated Tablets | Selexipag 1200mcg | Excella Gmbh, Germany | USA | 21 December 2015 | 21 December 2020 | 28 August 2018 | 5 years | 21 December 2020 |

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| 62. | MAL18086108ACRZ | Uptravi 1400 Microgram Film- Coated Tablets | Selexipag 1400mcg | Excella Gmbh, Germany | USA | 21 December 2015 | 21 December 2020 | 28 August 2018 | 5 years | 21 December 2020 |
| 63. | MAL18086107ACRZ | Uptravi 1600 Microgram Film- Coated Tablets | Selexipag 1600mcg | Excella Gmbh, Germany | USA | 21 December 2015 | 21 December 2020 | 28 August 2018 | 5 years | 21 December 2020 |

DCA: Drug Control Authority; DE: Data Exclusivity