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[REDACTED]

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**From:** s22 [REDACTED]  
**Sent:** Wednesday, 3 July 2019 2:28 PM  
**To:** SAS  
**Subject:** SAS Report from Paradigm Biopharmaceuticals Ltd [SEC=No Protective Marking]  
**Attachments:** 20190703 SAS report template v1.0\_Reporting Period 01Jan2019 - 30Jun2019[4].docx

Dear Sir / Madam,

Please find our SAS report covering the period 01 January 2019 to 30 June 2019.

If you have any questions, please let me know,

Kind regards,

s22 |

[REDACTED]  
[REDACTED]  
Paradigm Biopharmaceuticals Ltd  
Suite 1  
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517 Flinders Lane  
Melbourne VIC 3000  
AUSTRALIA

s22 [REDACTED]  
[REDACTED]

paradigm

Paradigm BioPharmaceuticals Ltd  
Level 2, 517 Flinders Lane  
Melbourne VIC 3000  
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Monday, 01 July 2019

Special Access Scheme  
Pharmacovigilance and Special Access Branch  
Therapeutic Goods Administration  
PO Box 100  
Woden ACT 2606  
Australia  
By email: SAS@health.gov.au

Dear TGA

**Re: Report on usage of pentosan polysulfate sodium (PPS) under the Special Access Scheme**

Please find attached a report for usage of PPS 100 mg/mL injection under the Special Access Scheme for the period 01 January 2019 to 30 June 2019.

During this period Paradigm has supplied PPS for use in 104 patients as shown in details on pages 2 - 6.

Please contact me if you would like further clarification.

Yours sincerely

s22

Paradigm BioPharmaceuticals Ltd

s22

## Usage of pentosan polysulfate sodium under the Special Access Scheme

Reporting period: 01 January 2019 to 30 June 2019

SAS approval number	Dosage regimen Dose/frequency/ duration)	Number of ampoules issued	Remaining ampoules returned or destroyed	Adverse reactions reported (Y/N). If yes provide ADR number
MB19/0117480	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0061613	2mg/kg twice weekly for four week	24	Yes, once treatment completed	No
MB18/060997	2mg/kg twice weekly for four weeks	16	Yes, once treatment completed	No
MB19/0104322	2mg/kg twice weekly for four weeks	24	Yes, once treatment completed	No
MB19/0107523	2mg/kg twice weekly for four weeks	16	Yes, once treatment completed	No
MB19/0111771	2mg/kg twice weekly for four weeks	24	Yes, once treatment completed	No
MB19/0112662	2mg/kg twice weekly for four weeks	24	Yes, once treatment completed	No
MB19/0107719	2mg/kg twice weekly for four weeks	24	Yes, once treatment completed	No
MB19/0107638	2mg/kg twice weekly for four weeks	24	Yes, once treatment completed	No
MB19/0115668	2mg/kg twice weekly for four weeks	24	Yes, once treatment completed	No
MB18/0047076	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0127578	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0039586	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0058469	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0047889	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0048478	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0052186	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0060149	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No

MB18/0059630	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0093448	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0060040	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0066412	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0084310	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0052085	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0048477	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0097739	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0103089	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0081197	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0067265	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0084296	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0044542	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0074933	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0054374	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0058154	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0086178	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0083318	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0073258	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0077245	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0062731	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0105205	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0071215	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0061000	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0074227	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No

MB18/0074931	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0079451	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0084010	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0108601	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0109621	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0108310	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0109196	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0114198	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0107635	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0035712	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0064628	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0064645	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0093810	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0091836	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0092321	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0087256	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0095609	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0100174	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0099011	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0097376	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0067657	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0073156	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0120222	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0108317	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0039084	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No

MB19/0121981	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0108603	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0050313	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB18/0068649	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB18/0066408	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB18/0060999	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB18/0077248	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB18/0077217	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB19/0097027	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB18/0060120	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB19/0111693	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB19/0095623	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB19/0102732	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB19/0100148	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB19/0119808	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB19/0111322	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB18/0082654	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB18/0083928	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB19/0121560	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB18/0058748	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0044540	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0087261	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0067391	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0097035	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0075576	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No



MB18/0064664	2mg/kg twice weekly for six weeks	16	Yes, once treatment completed	No
MB18/0089141	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0084733	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0079347	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/011020	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0072359	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0102913	2mg/kg twice weekly for six weeks	36	Yes, once treatment completed	No
MB18/0064836	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB18/0072155	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0115660	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No
MB19/0102499	2mg/kg twice weekly for six weeks	24	Yes, once treatment completed	No