

## Supplementary Information

### Safety, immunogenicity and interchangeability of biosimilar monoclonal antibodies and fusion proteins: a regulatory perspective

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**Supplementary Table 1: Comparison of administration devices, strengths and pharmaceutical forms of approved biosimilar monoclonal antibodies**

|            | Administration device | Strength          | Pharmaceutical form         | Humira | Amgevita,<br>Halimatoz,<br>Hefiya, Hyrimoz | Hulio,<br>Imraldi,<br>Idacio | Amsparity |
|------------|-----------------------|-------------------|-----------------------------|--------|--------------------------------------------|------------------------------|-----------|
| Adalimumab | Vial                  | 40 mg (50 mg/ml)  | Solution for injection (sc) | ✓      |                                            | ✓                            | ✓         |
|            | PFS                   | 20 mg (50 mg/ml)  | Solution for injection (sc) |        | ✓                                          |                              | ✓         |
|            | PFS                   | 20 mg (100 mg/ml) | Solution for injection (sc) | ✓      |                                            |                              |           |
|            | PFS                   | 40 mg (100 mg/ml) | Solution for injection (sc) | ✓      |                                            |                              |           |
|            | PFS                   | 40 mg (50 mg/ml)  | Solution for injection (sc) | ✓      | ✓                                          | ✓                            | ✓         |
|            | PFS                   | 80 mg (100 mg/ml) | Solution for injection (sc) | ✓      |                                            |                              |           |
|            | Pre-filled pen        | 40 mg (100 mg/ml) | Solution for injection (sc) | ✓      |                                            |                              |           |
|            | Pre-filled pen        | 40 mg (50 mg/ml)  | Solution for injection (sc) | ✓      | ✓                                          | ✓                            | ✓         |
|            | Pre-filled pen        | 80 mg (100 mg/ml) | Solution for injection (sc) | ✓      |                                            |                              |           |

|            | Administration device | Strength           | Pharmaceutical form                                   | Remicade | Flixabi,<br>Inflectra, Zessly | Remsima |
|------------|-----------------------|--------------------|-------------------------------------------------------|----------|-------------------------------|---------|
| Infliximab | Vial                  | 100 mg (100 mg/ml) | Powder for concentrate for solution for infusion (iv) | ✓        | ✓                             | ✓       |
|            | PFS                   | 120 mg (120 mg/ml) | Solution for injection (sc)                           |          |                               | ✓       |
|            | Pre-filled pen        | 120 mg (120 mg/ml) | Solution for injection (sc)                           |          |                               | ✓       |
|            |                       |                    |                                                       |          |                               |         |

|           | Administration device | Strength            | Pharmaceutical form                        | Mabthera | Blitzima,<br>Ritemvia,<br>Rixathon,<br>Riximyo,<br>Ruxience,<br>Truxima |
|-----------|-----------------------|---------------------|--------------------------------------------|----------|-------------------------------------------------------------------------|
| Rituximab | Vial                  | 100 mg (10 mg/ml)   | Concentrate for solution for infusion (iv) | ✓        | ✓                                                                       |
|           | Vial                  | 500 mg (10 mg/ml)   | Concentrate for solution for infusion (iv) | ✓        | ✓                                                                       |
|           | Vial                  | 1400 mg (120 mg/ml) | Solution for injection (sc)                | ✓        |                                                                         |
|           | Vial                  | 1600 mg (120 mg/ml) | Solution for injection (sc)                | ✓        |                                                                         |

| Trastuzumab | Administration device | Strength          | Pharmaceutical form                                   | Herceptin | Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera | Zercepac |
|-------------|-----------------------|-------------------|-------------------------------------------------------|-----------|-------------------------------------------------|----------|
|             | Vial                  | 150 mg (21 mg/ml) | Powder for concentrate for solution for infusion (iv) | ✓         | ✓                                               | ✓        |
|             | Vial                  | 420 mg (21 mg/ml) | Powder for concentrate for solution for infusion (iv) |           | ✓                                               |          |
|             | Vial                  | 600 mg (30 mg/ml) | Solution for injection (sc)                           | ✓         |                                                 |          |

| Bevacizumab | Administration device | Strength          | Pharmaceutical form                        | Avastin | Mvasi, Zirabev, Aybintio, Equidacent |
|-------------|-----------------------|-------------------|--------------------------------------------|---------|--------------------------------------|
|             | Vial                  | 100 mg (25 mg/ml) | Concentrate for solution for infusion (iv) | ✓       | ✓                                    |
|             | Vial                  | 400 mg (25 mg/ml) | Concentrate for solution for infusion (iv) | ✓       | ✓                                    |

| Etanercept | Administration device | Strength         | Pharmaceutical form                                | Enbrel | Nepexto, Benepali, Erelzi |
|------------|-----------------------|------------------|----------------------------------------------------|--------|---------------------------|
|            | Vial                  | 25 mg            | Powder for solution for injection (sc)             | ✓      |                           |
|            | Vial + PFS            | 10 mg (10 mg/ml) | Powder and solvent for solution for injection (sc) | ✓      |                           |
|            | Vial + PFS            | 25 mg (25 mg/ml) | Powder and solvent for solution for injection (sc) | ✓      |                           |
|            | PFS                   | 25 mg (50 mg/ml) | Solution for injection (sc)                        | ✓      | ✓                         |
|            | PFS                   | 50 mg (50 mg/ml) | Solution for injection (sc)                        | ✓      | ✓                         |
|            | Pre-filled pen        | 25 mg (50 mg/ml) | Solution for injection (sc)                        | ✓      |                           |
|            | Pre-filled pen        | 50 mg (50 mg/ml) | Solution for injection (sc)                        | ✓      | ✓                         |



