

| 000000000000000000000000000000000000000   |
|---|
|   |
|   |
|   |
| 1. DSM-IV000000000000000000000000000000000000   |
| $2. \   \Box$ |
| 4mg/6   |
| 24mg/6  |
| 0000015mg/000600000   |
| 000000400mg/000600000   |
| 0000000000GAF0004100000000000000000   |
| 3. 0000000180006500000<br>4. 0000   |
| 5. Visit1BPRS45<br>6  |
|   |
| 43[]  |
|   |

| 0000<br>0000012.5mg0101000000000000000000000000000000000                                |
|---|
|   |
| 1. 4000000000000000000000000000000000000  |
| 00000<br>00000000020000000000000000000000   |
| 0000<br>00024000003000000210000002000000000000400                                       |
| COCCOCCOCCOCCOCCOCCOCCOCCOCCOCCOCCOC  |
|   |
|   |
|   |
| 1. BPRS_Brief Psychiatric Rating ScaleBPRS20%   |
| 001800 <sup>0</sup> 00000001.00002.0000003.00004.000005.0000006.0000007.000007<br>00000 |
| 00000000000000000000000000000000000000  |
| 2.  |

| CGI-C  |
|--|
| 3. DDDDDClinical Global Impression of SeverityDCGI-SD                                |
|  |
| CGI-SDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDD  |
|  |
| DIEPSS□Drug Induced Extra-Pyramidal Symptoms Scale□ □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□ |
|  |
| BPRSDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDDD   |
|  |
| BPRS000000000000BPRS00000000000000000000   |
|  |
| Image  |
|  |
|  |

## 患者背景

| 背景因子 | カテゴリー        | 例数(N=43)<br>n(%) |
|------|--------------|------------------|
| 性別   | 男            | 23 (53.5)        |
|      | 女            | 20 (46.5)        |
| 年齢   | 18歳以上30歳未満   | 4(9.3)           |
|      | 30歳以上40歳未満   | 20 (46.5)        |
|      | 40歲以上        | 19 (44.2)        |
|      | 平均值(標準偏差)    | 39.0 (8.96)      |
|      | 中央値(最小値~最大値) | 38.0 (22~60)     |
| 罹病期間 | 10年未満        | 6(14.0)          |
|      | 10年以上20年未満   | 22(51.2)         |
|      | 20年以上        | 15 (34.9)        |
|      | 平均值(標準偏差)    | 17.6(7.8)        |
|      | 中央値(最小値~最大値) | 18.0(3.7~40.0)   |

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## 

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### **Image**

# 副作用(クロザリルとの関連が疑われる有害事象)(発現率20%以上のみ)

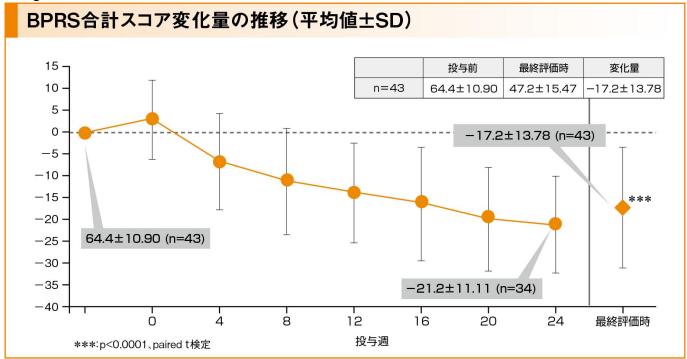
| WAR ALL ADDA DT          | N-43      |
|--------------------------|-----------|
| 副作用(MedDRA PT)           | n(%)      |
| 副作用発現症例数                 | 42 (97.7) |
| 傾眠                       | 32(74.4)  |
| 流差過多                     | 18 (41.9) |
| 便秘                       | 15(34,9)  |
| アラニン・アミノトランスフェラーゼ(ALT)増加 | 11 (25.6) |
| 悪心                       | 10 (23.3) |
| 嘔吐                       | 9 (20.9)  |
| 白血球数增加                   | 9(20.9)   |

24週間の治験期で認められた事象

#### 

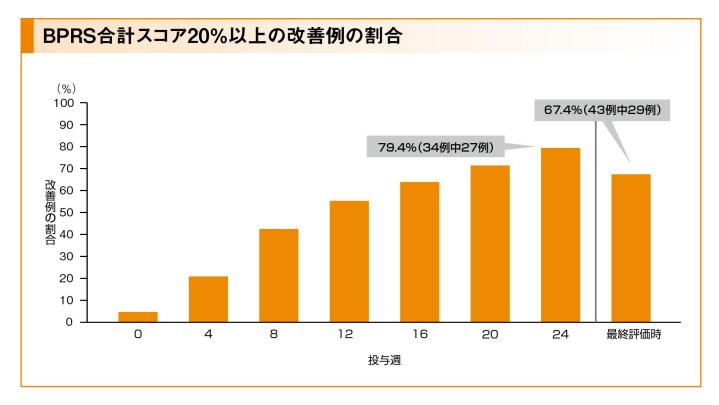
 $\begin{aligned} & \mathsf{BPRS} \\ & = & \mathsf{10.90} \\ & = & \mathsf{11.33} \\ & = & \mathsf{12.12} \\ & = & \mathsf{11.11} \\ & = & \mathsf{10.90} \\ & = &$ 

### Image



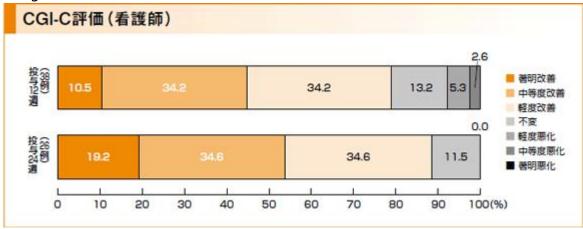
### 000000BPRS0000200000000000

Image



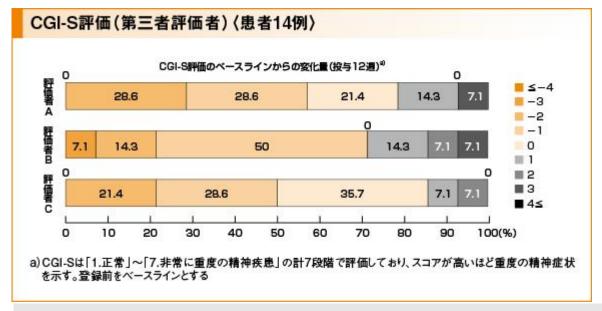
## \_\_\_\_CGI-C

#### **Image**



## 

#### **Image**



mailto:clozaril.remote@novartis.com

Source URL: https://www.pro.novartis.com/jp-ja/products/clozaril/clinical/02