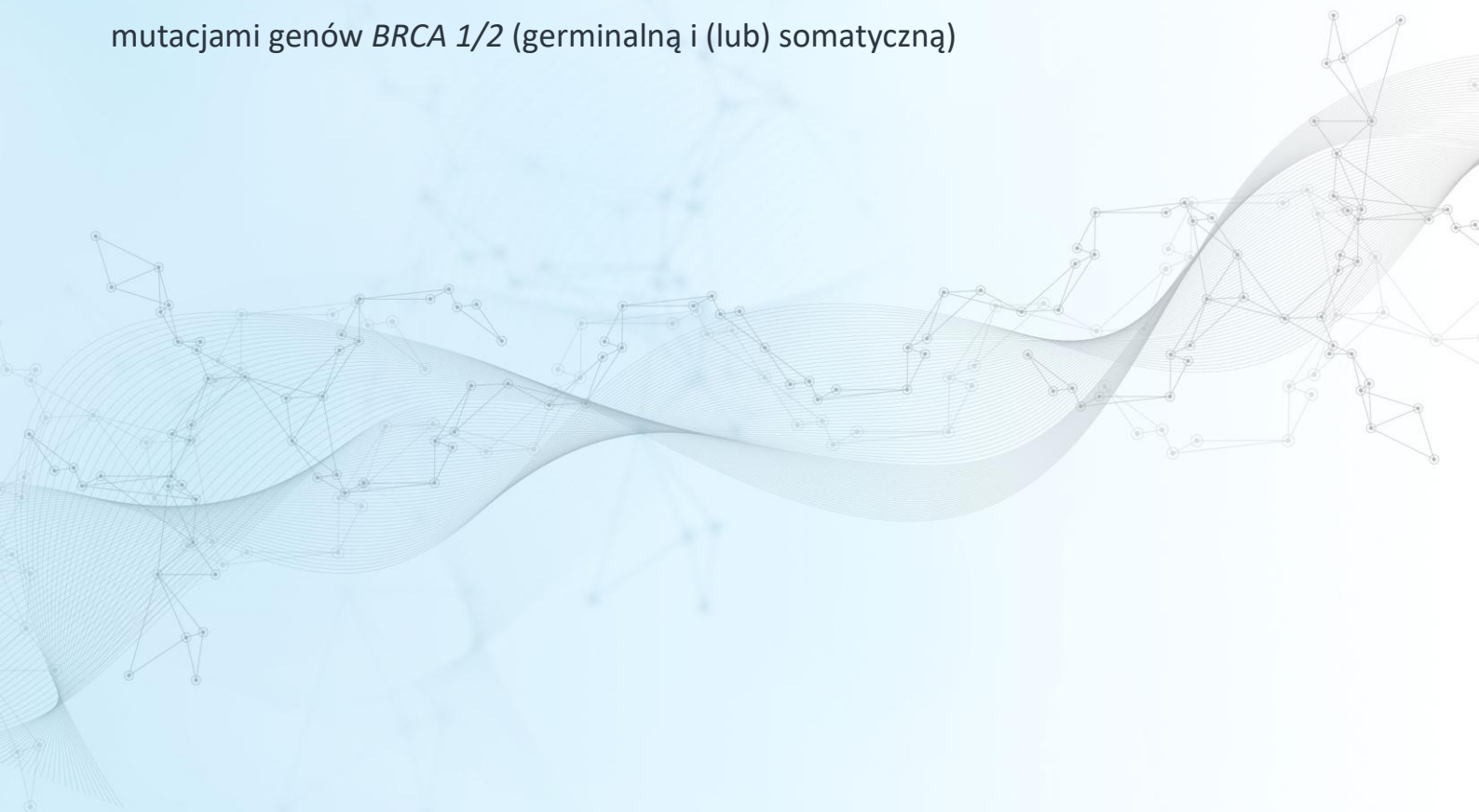


Odpowiedzi na uwagi do analiz w zakresie niespełnienia minimalnych wymagań – Załącznik 2

Akeega (niraparib + octan abirateronu)

w skojarzeniu z prednizonem lub prednizolonem i ADT w leczeniu dorosłych chorych na hormonowrażliwego raka gruczołu krokowego z przerzutami (mHSPC/ mCSPC) i mutacjami genów *BRCA 1/2* (germinalną i (lub) somatyczną)



Wykonawca

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E-mail: biuro@aestimo.eu

1 NIR+AAP+ADT vs zdefiniowane komparatory – metaanaliza sieciowej (NMA) w populacji ogólnej (ITT)

1.1 Podsumowanie oceny możliwości przeprowadzenia porównania pośredniego

[Redacted text block]

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[REDACTED]

[REDACTED]

1.2 Wyniki przeglądu systematycznego badań klinicznych

[REDACTED]

Akeega
(niraparyb + octan abirateronu)

w skojarzeniu z prednizonem lub prednizolonem i ADT w leczeniu dorosłych chorych na hormonowrażliwego raka gruczołu krokowego z przerzutami (mHSPC/ mCSPC) i mutacjami genów BRCA 1/2 (germinalną i (lub) somatyczną)

Tabela 2.



[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

	2019	2020
Overall	100%	100%
Category A	85%	90%
Category B	75%	80%
Category C	65%	70%
Category D	55%	60%
Category E	45%	50%
Category F	35%	40%
Category G	25%	30%
Category H	15%	20%
Category I	10%	15%
Category J	5%	10%

[illegible]

Tabela 4.

Country	Year	Population (millions)	Urban population (millions)	Urban population (%)
Algeria	2000	24.0	14.0	58.3
Algeria	2001	24.2	14.2	58.7
Algeria	2002	24.4	14.4	59.0
Algeria	2003	24.6	14.6	59.4
Algeria	2004	24.8	14.8	59.7
Algeria	2005	25.0	15.0	60.0
Algeria	2006	25.2	15.2	60.3
Algeria	2007	25.4	15.4	60.6
Algeria	2008	25.6	15.6	60.9
Algeria	2009	25.8	15.8	61.2
Algeria	2010	26.0	16.0	61.5
Algeria	2011	26.2	16.2	61.8
Algeria	2012	26.4	16.4	62.1
Algeria	2013	26.6	16.6	62.4
Algeria	2014	26.8	16.8	62.7
Algeria	2015	27.0	17.0	63.0
Algeria	2016	27.2	17.2	63.2
Algeria	2017	27.4	17.4	63.5
Algeria	2018	27.6	17.6	63.8
Algeria	2019	27.8	17.8	64.0
Algeria	2020	28.0	18.0	64.3

w skojarzeniu z prednizonem lub prednizolonem i ADT w leczeniu dorosłych chorych na hormonowrażliwego raka gruczołu krokowego z przerzutami (mHSPC/ mCSPC) i mutacjami genów BRCA 1/2 (germinalną i (lub) somatyczną)

Country	Year	Population (millions)	Urban population (millions)	Urban population (%)
Algeria	2000	24.0	10.0	41.7
Algeria	2005	26.0	11.0	42.3
Algeria	2010	28.0	12.0	42.9
Algeria	2015	30.0	13.0	43.3
Algeria	2020	32.0	14.0	43.8
Algeria	2025	34.0	15.0	44.1
Algeria	2030	36.0	16.0	44.4
Algeria	2035	38.0	17.0	44.7
Algeria	2040	40.0	18.0	45.0
Algeria	2045	42.0	19.0	45.2
Algeria	2050	44.0	20.0	45.5
Algeria	2055	46.0	21.0	45.7
Algeria	2060	48.0	22.0	45.8
Algeria	2065	50.0	23.0	46.0
Algeria	2070	52.0	24.0	46.2
Algeria	2075	54.0	25.0	46.3
Algeria	2080	56.0	26.0	46.4
Algeria	2085	58.0	27.0	46.5
Algeria	2090	60.0	28.0	46.7
Algeria	2095	62.0	29.0	46.8
Algeria	2100	64.0	30.0	46.9

[REDACTED]

1.3 Metodyka porównania pośredniego

1.3.1 Charakterystyka badań uwzględnionych w ramach metaanalizy sieciowej

[REDACTED]

[REDACTED]

1.3.1.1 Ocena kryteriów włączenia i wykluczenia

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

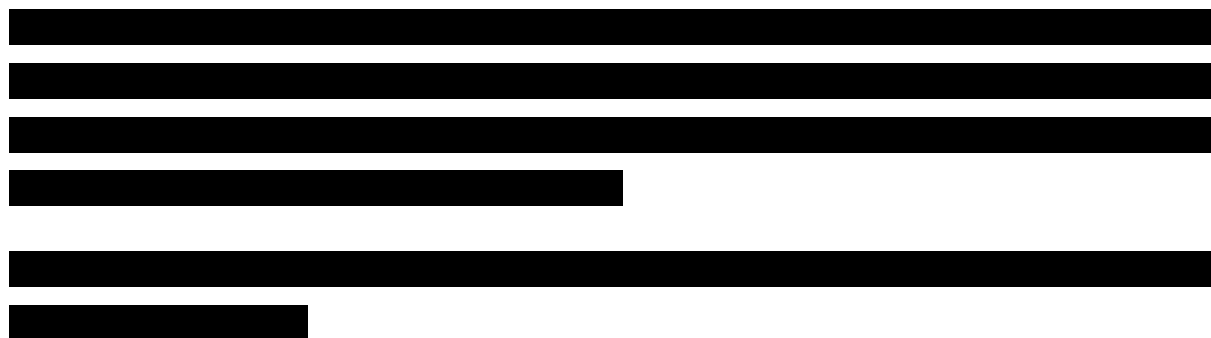
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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[illegible]



[illegible]

[REDACTED]

[REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]

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Tabela 8. [Redacted text]

[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
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[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

Grupa	Wiek	Sex	Przerzuty	BRCA1/2	BRCA1/2	BRCA1/2	BRCA1/2	BRCA1/2
A	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
B	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
C	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
D	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
E	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
F	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
G	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
H	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
I	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
J	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
K	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
L	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
M	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
N	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
O	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
P	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
Q	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
R	65-74	M	0	0	0	0	0	0
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S	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
T	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
U	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
V	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
W	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
X	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
Y	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0
Z	65-74	M	0	0	0	0	0	0
	75-84	M	0	0	0	0	0	0

1.3.1.4 Ocena punktów końcowych oraz ryzyka wystąpienia błędów systematycznych w badaniach

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[REDACTED]

1.3.2 Oceniane punkty końcowe

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Tabela 9. [REDACTED]

[REDACTED]												
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Akeega
(niraparyb + octan abirateronu)

w skojarzeniu z prednizonem lub prednizolonem i ADT w leczeniu dorosłych chorych na hormonowrażliwego raka gruczołu krokowego z przerzutami (mHSPC/ mCSPC) i mutacjami genów BRCA 1/2 (germinalną i (lub) somatyczną)

[REDACTED]

[REDACTED]

[REDACTED]

1.4 Skuteczność kliniczna

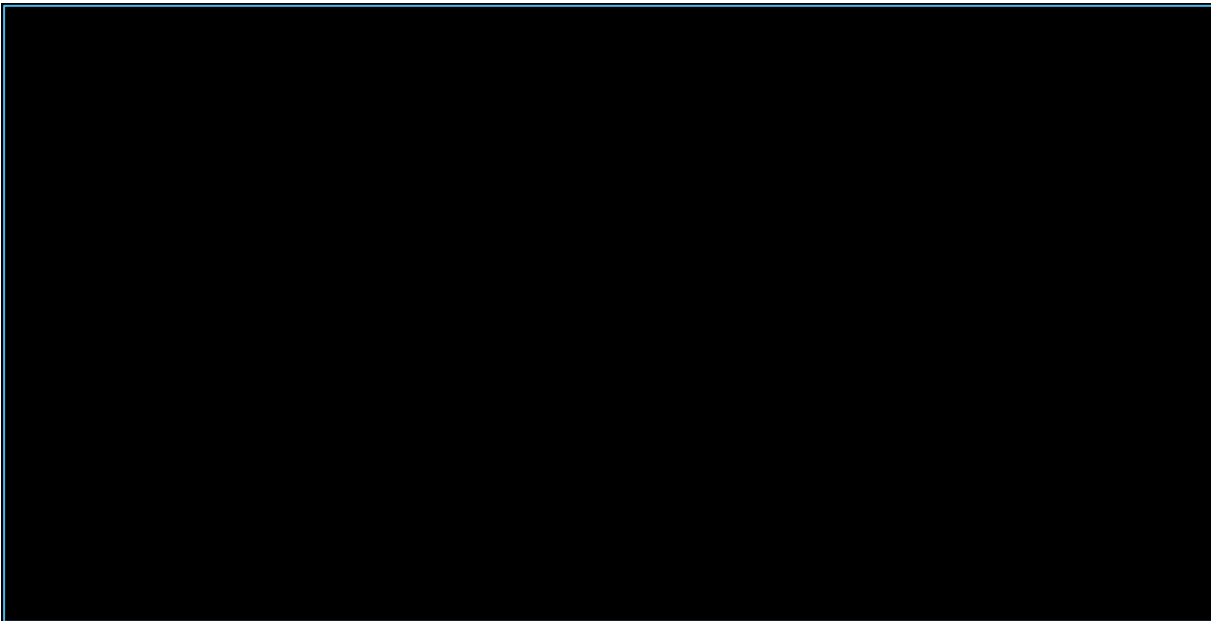
[REDACTED]

1.4.1 [REDACTED]

1.4.1.1 [REDACTED]

[REDACTED]

Wykres 2.



[Redacted text block]

Tabela 10.

[Redacted text block]

[Redacted text block]

Wykres 3. [Redacted text]



[Redacted text block]

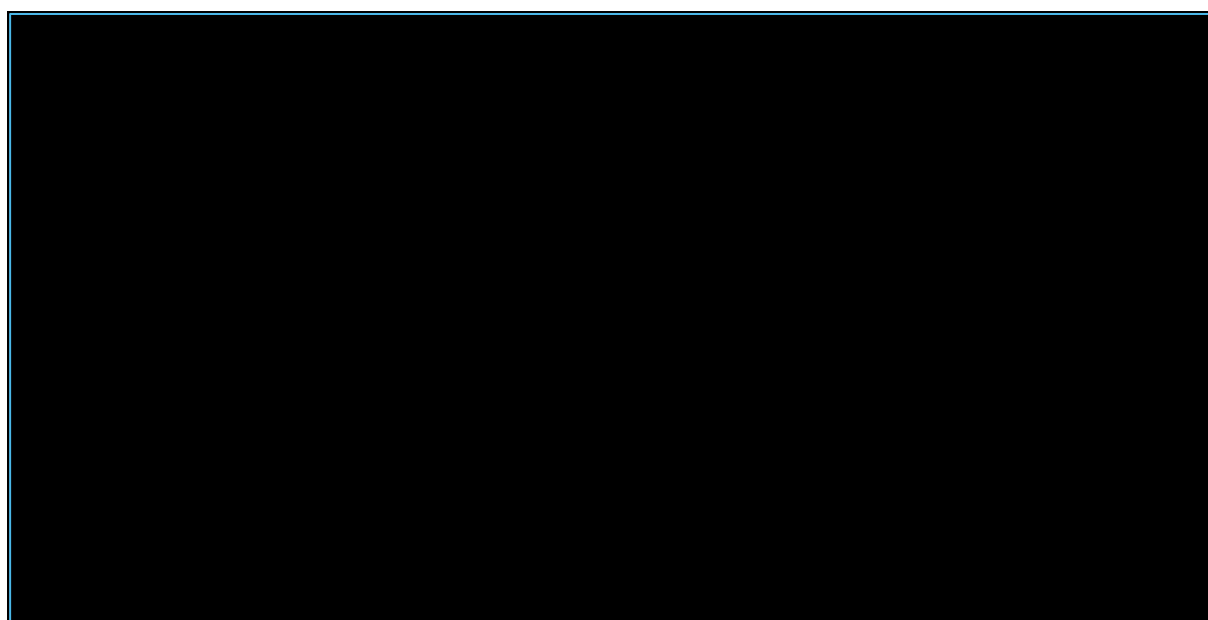
Tabela 11. [Redacted text]

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[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
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[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]

1.4.1.2

[Redacted text block]

Wykres 4.



[Redacted text block]

Wykres 6. [redacted]



[redacted]

[redacted]

[redacted]

[redacted]

Tabela 14. [redacted]

[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
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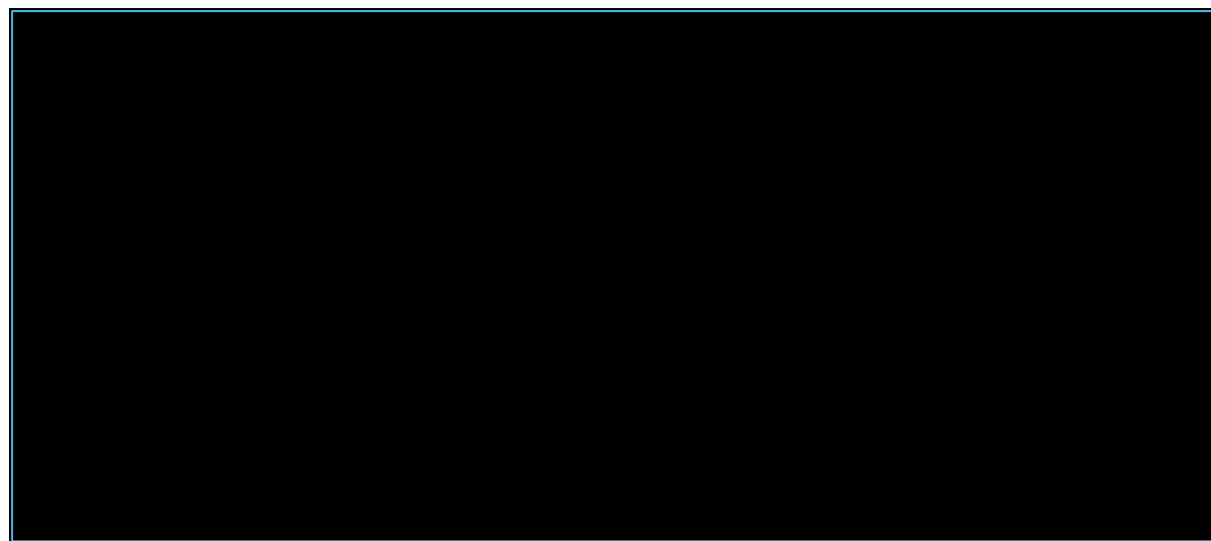
[redacted]

[redacted]

[redacted]

[redacted]

[redacted]



	1	2	3	4	5	6	7
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2	1	2	3	4	5	6	7
3	1	2	3	4	5	6	7
4	1	2	3	4	5	6	7
5	1	2	3	4	5	6	7
6	1	2	3	4	5	6	7
7	1	2	3	4	5	6	7

w skojarzeniu z prednizonem lub prednizolonem i ADT w leczeniu dorosłych chorych na hormonowrażliwego raka gruczołu krokowego z przerzutami (mHSPC/ mCSPC) i mutacjami genów BRCA 1/2 (germinalną i (lub) somatyczną)

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3	4	5	6	7	8	9
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71	72	73	74	75	76	77
72	73	74	75	76	77	78
73	74	75	76	77	78	79
74	75</					

1.5 Wnioski końcowe

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

