

Equity Research

Johnson & Johnson

JNJ: Xtandi Continued Lead Zytiga In Overall Share In May

• **Summary:** We reviewed May 2015 data from AlphaImpactRx (formerly Symphony Health) survey and IMS for JNJ's Zytiga and competing prostate cancer drugs. May was the first-time in this survey that competitor Xtandi led Zytiga in overall, pre-chemo and post-chemo market shares among sample oncologists. Specifically, Zytiga's overall share among sample oncologists fell 250bps to 29% from April to May, remaining behind Xtandi's more modest share decline of 40bps to 31% over the same period. Zytiga TRx (total prescription) volume decline accelerated to high-single digit from low- to mid-single digit decline earlier in the year while NRx (new prescription) volume continued to fall in the low-double digits. Among sample urologists, Xtandi also moved ahead of Zytiga with 26% share vs. Zytiga's 23% share for the rolling three-months through May. While Zytiga's label was updated in March to include positive OS (overall survival) benefit data in the pre-chemo population, the enhancement does not appear to be adding a boost to the franchise. While we expect price increases and greater OUS (outside of the U.S.) penetration to drive Zytiga growth in 2015, we expect the growth to remain modest due to increased competition. We model Zytiga sales of \$1.1B (+8%) in the U.S. and \$2.3B (+11%) globally in 2015. In terms of life cycle management, JNJ is studying ARN-509, which may have broader spectrum of disease activity, in Phase 3 studies as both monotherapy and in combination therapy with Zytiga. The drug could be launched as early as 2018.

• **Xtandi led Zytiga in overall, pre-chemo and post-chemo market shares in May.** Zytiga's share among sample oncologists in the overall CRPC (castration resistant prostate cancer) market fell by 250bps to 29% in May (Figure 1). This compares to JNJ's estimate of Q1 overall U.S. CRPC market share of 30.3%, down 1.2 points sequentially due to increased competition. Key competitor Xtandi's overall share fell by 40bps to 31% in May, staying ahead of Zytiga for the second consecutive month. DNDN/VRX's Provenge share fell by about 100bps to 3% while Bayer/Algeta's Xofigo share rose by 100bps to nearly 5%. In the pre-chemo segment, Zytiga's share fell to below 35% in May from 39% in April, for the first-time trailing Xtandi whose share fell to 35% in May from 36% in April (Figure 3). In the post-chemo segment, Zytiga share rose to 21% in May from 19% in April, while Xtandi share rose 70bps to over 34% during the same period. Over the past year, the increasing use of Zytiga and Xtandi in the pre-chemo segment has pushed Taxotere into a market leading position in the post-chemo prostate market with roughly one-third market share (Figure 4). Both Zytiga and Xtandi usage in pre-chemo stood at 70% or higher in May (Figure 5). During the six months through May, Zytiga's usage as first-line therapy was 67%, which was still far ahead of Xtandi's 43% first-line use (Figure 6).

• **Continued on the following page.**

Valuation Range: \$128.00 to \$130.00

Our valuation range of \$128-\$130 implies about 20x our 2016E cash EPS of \$6.47 and is mainly based on a sum-of-the-parts analysis. Risks include delays to pipeline products, additional product recalls and unexpected deterioration in the industry.

Investment Thesis:

We believe that JNJ is positioned for solid growth, driven by strength of its pharmaceuticals business, recovery in the consumer segment and market stabilization coupled with share gain in MD&D.

Please see page 10 for rating definitions, important disclosures and required analyst certifications
All estimates/forecasts are as of 06/29/15 unless otherwise stated.

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Outperform

Sector: Diversified
Market Weight

Company Note

	2014A	2015E		2016E	
		Curr.	Prior	Curr.	Prior
CASH EPS					
Q1 (Mar.)	\$1.63	\$1.56 A	NC	NE	
Q2 (June)	1.78	1.67	NC	NE	
Q3 (Sep.)	1.61	1.47	NC	NE	
Q4 (Dec.)	1.37	1.44	NC	NE	
FY	\$6.39	\$6.14	NC	\$6.47	NC
CY	\$6.39	\$6.14		\$6.47	
FY P/E	15.3x	15.9x		15.1x	
Rev.(MM)	\$74,331	\$70,621		\$73,091	

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters
 NA = Not Available, NC = No Change, NE = No Estimate, NM = Not Meaningful
 V = Volatile, * = Company is on the Priority Stock List

EPS excludes amortization expense.

2014 excludes \$0.42 of amortization.

2015 excludes \$0.32 of amortization.

Ticker	JNJ
Price (06/29/2015)	\$97.68
52-Week Range:	\$95-110
Shares Outstanding: (MM)	2,875.0
Market Cap.: (MM)	\$280,830.0
S&P 500:	2,057.64
Avg. Daily Vol.:	7,559,850
Dividend/Yield:	\$2.28/2.3%
LT Debt: (MM)	\$18,400.0
LT Debt/Total Cap.:	17.5%
ROE:	27.0%
3-5 Yr. Est. Growth Rate:	6.0%
CY 2015 Est. P/C. EPS-to-Growth:	2.6x
Last Reporting Date:	04/14/2015
	Before Open

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters

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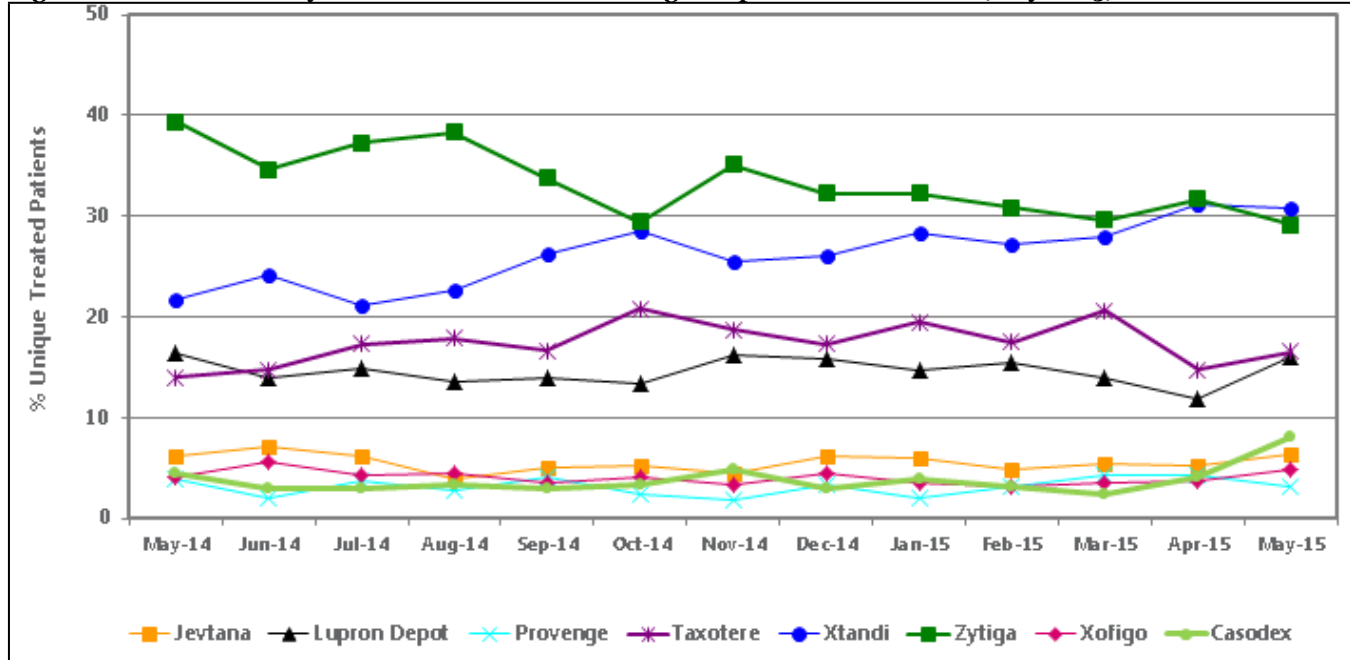
Together we'll go far



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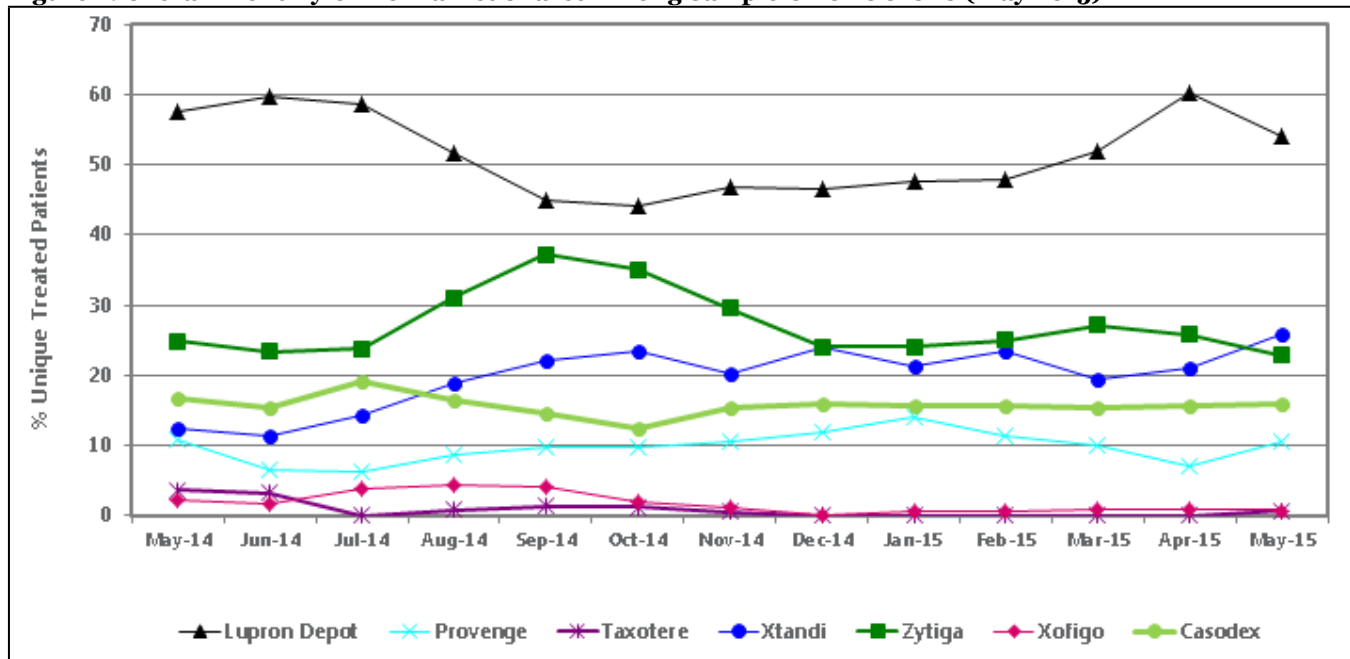
- **Zytiga share among sample urologists dipped while Xtandi moved ahead.** Urologists are key prescribers in the pre-chemo segment of the market. On a rolling 3-month basis through May, Zytiga held a 23% market share, down from 26% in April while Xtandi moved ahead from 21% in April to 26% in May (Figure 2). However, hormone therapy (ADT or androgen deprivation therapy) remained the clear market leader among the sample urologists, with Lupron Depot holding 54% rolling 3-month share (vs. 58% average share a year ago). Casodex's rolling 3-month share was largely steady around 16%. The key caveat we highlight here is the small sample size of on average 50 urologists each month compared to about 150 oncologists in the survey. As such, AlphaImpactRx provides the urologist share data on a rolling 3-months basis while the oncologist data are shown monthly.
- **Zytiga new prescription (NRx) volume decline largely holding steady while TRx volume decline accelerated.** Weekly Zytiga Rx volume continued to decline in the US (Figure 7-8), with TRx volume decline accelerating somewhat in the recent weeks despite an enhanced label that includes OS benefit. For the 4-week period ended 6/12/15, Zytiga TRx totaled 8,378, -10% yr/yr, while 4-week NRx totaled 2,415, down 14% yr/yr. Given the competition, we expect to see continued dampening in Zytiga Rx growth.
- **No discernable impact from recent Zytiga label enhancement.** At the end of March, FDA approved adding overall survival (OS) benefit from the COU-AA-302 study in pre-chemo prostate cancer patients in the Zytiga label while the data was also published in the February 2015 issue of The Lancet Oncology. The data showed that Zytiga plus prednisone provides a statistically significant OS benefit vs. prednisone alone (median OS 34.7 vs. 30.3 months; $p=0.0033$). Previously, MDVN had touted Xtandi as the only new prostate cancer drug with significant OS and rPFS benefit. However, the label enhancement does not appear to be having a meaningful impact in driving Zytiga share or demand volume.
- **ARN-509 remains attractive long-term growth opportunity.** Long term, we continue to see ARN-509, currently in Phase 3 development as monotherapy and combination therapy with Zytiga, as an important growth driver with approval/launch possible in 2018. ARN-509 is a second-generation androgen receptor signaling inhibitor with a mechanism of action that may be complimentary to current therapies like Zytiga and Xtandi. The compound represents the next leg of growth potential in JNJ's prostate cancer franchise with potentially broader utility and a longer patent life. We understand that the issued US composition of matter of patent expires in 2028 (before extension) while the EU patent goes out to 2027. Although these two Phase 3 studies are expected to complete in December 2016 and December 2018, we understand that the studies include opportunities for interim looks that may allow for early termination of the studies on exceptional data (or safety concerns). We assume that ARN-509 reaches the market in 2018 and our model includes risk-adjusted sales of \$200MM in 2018 and \$475MM in 2019.
- **We assume modest Zytiga sales growth in 2015.** Zytiga was one of JNJ's best new drug launches with global sales totaling \$2.2B or 26% ex-FX growth in 2014, its fourth year on the market. Q1 2015 US Zytiga sales of \$253MM represented nearly 11% yr/yr growth, a deceleration from growth of 21% in Q4 and 30% in full year 2014. Q1 represented only the second time that US Zytiga sales fell sequentially (first time was in 4Q12 and reflected adjustments related to the start of a patient assistance program). OUS Zytiga sales of \$303MM represented 26% ex-FX growth, down modestly from +30% in Q4 and +36% in full year 2014. According to JNJ, the U.S. prostate cancer market grew 12.5% in Q1, vs. +15% in Q4 and +11% in the first 9 months of 2014. Zytiga held 30% share in Q1, down 1.2 points Q/Q due to increased competition, largely from Xtandi approval in the pre-chemo segment in late 2014. OUS Zytiga growth was driven by additional country launches with the drug now approved in over 95 countries. We expect that overall market growth, further pre-chemo penetration, price increase (JNJ has taken 7-8% price increase per year the last 3 years) and additional OUS uptake to drive 2015 Zytiga growth, albeit at a more modest pace. We model 2015 Zytiga sales of \$2.3B or 11% ex-FX growth WW and \$1.1B or 8% growth in the US. Our market model (Figure 9) reflects aggregate results for primarily newer agents approved for CRPC (i.e. excludes Lupron Depot, Taxotere, etc).
- **Caveats about AlphaImpactRx survey:** 1) Small physician sample size; 2) post-chemo represents 50%+ of the survey market even though there are 2-3x as many pre-chemo patients--likely due to concentration of oncologists in the survey, who prescribe more for post-chemo; 3) inclusion of supportive care products likely understates brand share; 4) overall share trend may show small discrepancy (+/- 1%) to the pre- and post-chemo share trends due to inclusion of "unknown" chemo status patients in the overall population.

Figure 1. Overall Monthly CRPC Market Shares Among Sample ONCOLOGISTS (May 2015)



Source: AlphaImpactRx's BrandImpact.

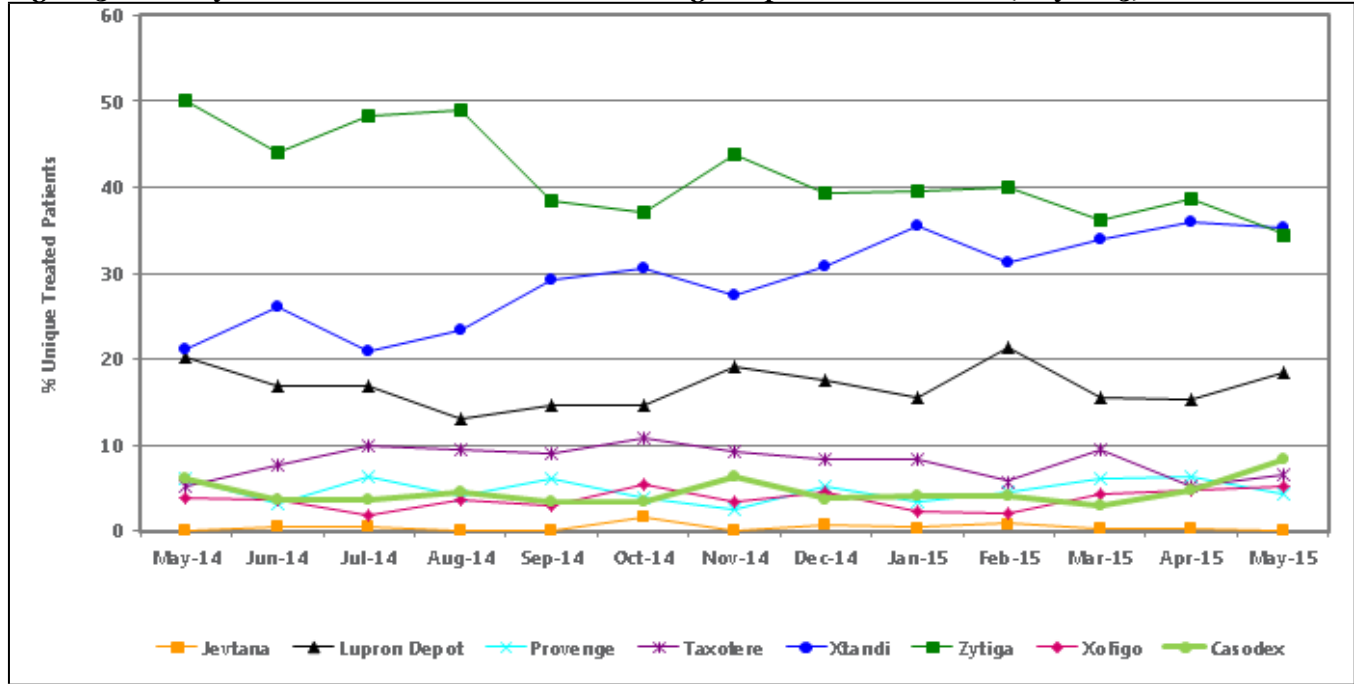
Figure 2. Overall Monthly CRPC Market Shares Among Sample UROLOGISTS (May 2015)



Source: AlphaImpactRx's BrandImpact.

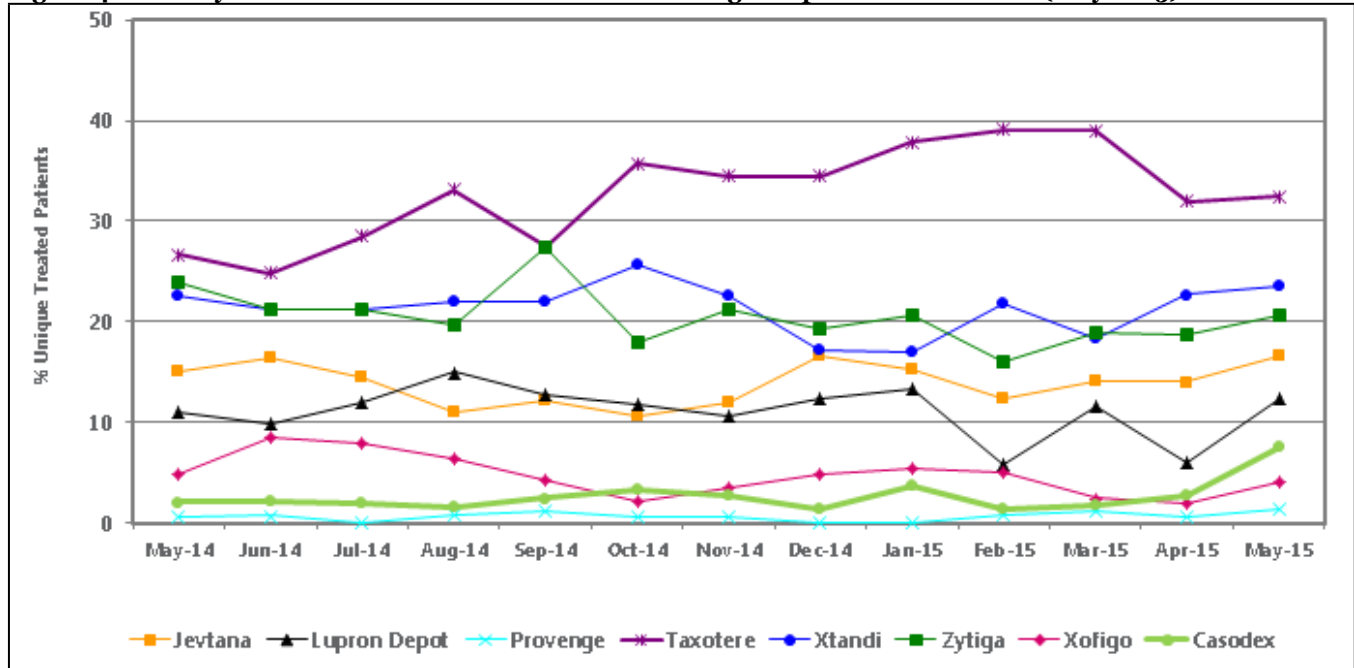
Medical Technology

Figure 3. Monthly Chemo-Naïve CRPC Mkt Share Among Sample ONCOLOGISTS (May 2015)



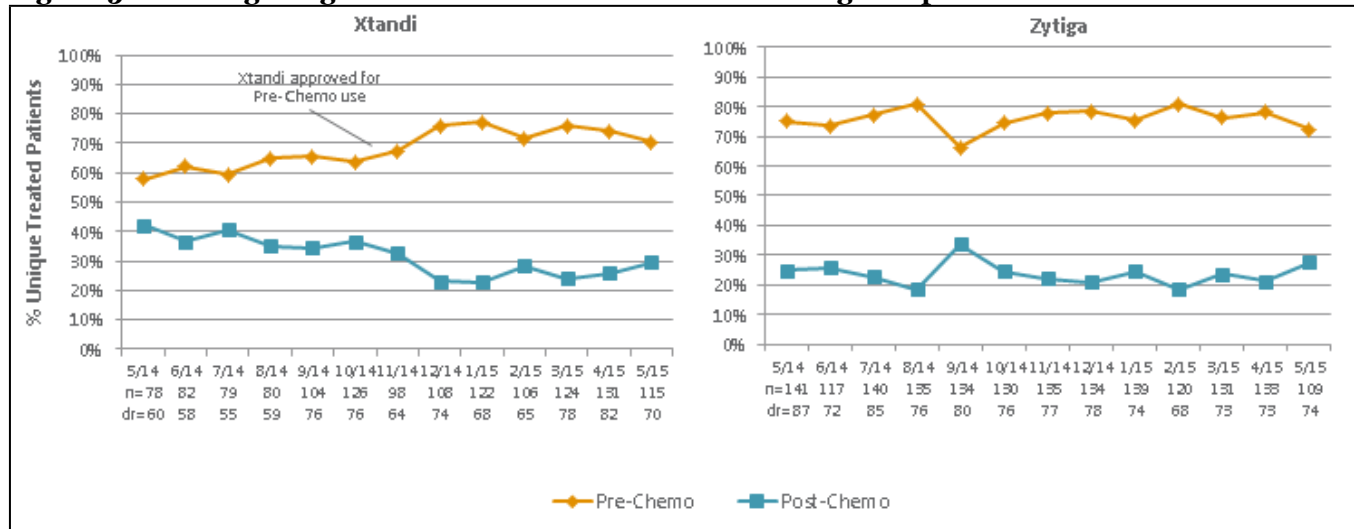
Source: AlphaImpactRx's BrandImpact.
Note that Zytiga was approved for pre-chemo naïve use in September 2014.

Figure 4. Monthly Post-Chemo CRPC Market Shares Among Sample ONCOLOGISTS (May 2015)



Source: AlphaImpactRx's BrandImpact.

Figure 5. Growing Usage in Pre-Chemo CRPC Market Among Sample ONCOLOGISTS



Source: AlphaImpactRx's BrandImpact.

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